SCALE-UP PLAN FOR ESSENTIAL MEDICINES FOR CHILD HEALTH

Diarrhea, Pneumonia and Malaria

PAKISTAN

Gul-e-Shehwar Zahid, Jai K Das & Zulfiqar A Bhutta

AGA KHAN UNIVERSITY KARACHI

Abbreviations

ACT	Artemisinin-Combination Therapy
ARI	Acute Respiratory Illness
BFHI	Baby Friendly Hospital Initiative
BHUs	Basic Health Units
CDD	Control of Diarrhoeal Diseases
CME	Continued Medical Education
CSR	Corporate Social Responsibility
DHQs	District Headquarters
DHS	Demographic Health Survey
DOH	Departments of Health
DRAP	Drug Regulatory Agency of Pakistan
DTU	Diarrhoea Treatment Units
EDL	Essential Drug List
EML	Essential Medicines List
EMR	Eastern Mediterranean Region
EPI	Expanded Program of Immunization
FMG	Fast Moving Goods
GAVI	Global Alliance for Vaccines and Immunization
GDP	Good Distribution Practices
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GP	General Practitioners
HMIS	Health Management Information System
IMCI	Integrated Management of Childhood Illnesses
IPR	Intellectual Property Rights
IRS	Indoor Residual Spraying
ITN	Insecticide-Treated Nets
LHS	Lady Health Supervisor
LHV	Lady Health Visitor
LHW	Lady Health Worker
LLIN	Long Lasting Insecticide Nets
LMIC	Low and Middle Income Countries
MCHC	Maternal and Child Health Centers
MDG	Millennium Development Goals
MNCH	Maternal, Neonatal and Child Health
MOH	Ministry of Health
MPR	Median Price Ratio
NCHD	National Commission for Human Development
NGO	Non-Government Organization
NID	National Immunization Days
NIH	National Institute of Health
NNS	National Nutrition Survey
NRSP	National Rural Support Program
NSP	Non-Severe Pneumonia
NWFP	North West Frontier Province
OECD	Organization of Economic Cooperation and Development
OKS	Ural Rehydration Solution
UKI	Ural Rehydration Therapy
PDHS	Pakistan Demographic Health Survey
PKR	Pakistan Rupees

- POUZN Point-of-Use Disinfection and Zinc Treatment
- PPHI People's Primary Healthcare Initiative
- RBM Roll Back Malaria
- RCT Randomized Control Trial
- RDT Rapid Diagnostic Tool
- RHC Rural Health Centers
- SMS Short Message Service
- SMX Sulfamethaoxazole
- THQs Tehsil/Taluka Headquarters
- TMP Trimethoprim
- UN United Nations
- UNDP United Nations Development Fund
- UNICEF United Nations International Child Emergency Fund
- WHO World Health Organization
- WTO World Trade Organization

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EXECUTIVE SUMMARY

With an under-five mortality rate of 89 per 1000 live births, Pakistan is lagging behind the desired MDG 4. There is still a need to reduce the under-five mortality rate by 45 percentage points in order to achieve the MDG target by 2015. This seems to be an improbable outcome considering the recent trends and a persistent rate of under five deaths since the past decade. Each year around 91,000 and 53,300 children die from pneumonia and diarrhea respectively, in Pakistan. Diarrhea, pneumonia and malaria collectively contribute to around 50% of deaths in children. These three diseases, thus, represent a challenging but surmountable obstacle towards achieving the MDG 4 target. Implementation of large-scale interventions and scale-up plan focusing on these three major killers of children in Pakistan is essential.

Lack of access to appropriate management and medicines are amongst the major contributors to the high rate of mortality from diarrhea, pneumonia and malaria in Pakistan. Only 37% of children suffering from diarrhea receive ORS and only 2.8% receive zinc. About half of children suffering from suspected pneumonia receive an antibiotic and only 3% of children having fever receive an anti-malarial. These figures show that lack of access to essential medicines is a major barrier to reduce the burden of these diseases.

This report identifies the major barriers towards accessing essential medicines by care givers. Interventions are required at all the three levels: public, private and community in order to improve access. There seems to be a significant knowledge-practice gap in the use of ORS for diarrhea. 91% of mothers have heard about ORS but only 2.5% have it available in their homes. Pharmaceutical industries are not primarily interested in producing ORS due to its low cost and do not appreciate the demand for ORS and zinc. Partnering with these industries can help them acknowledge the demand for essential medicines and expanding access of these medicines to far flung and remote areas. The demand side can also be further strengthened through home visits by LHWs and imparting health messages for improving care giver knowledge and treatment these childhood diseases through radio, short message service (SMS) and cable TV channels.

National Drug Policy covers selection of essential medicines, medicines pricing, procurement, distribution, regulation, pharmaco-vigilance, rational use of medicines, human resource development, research, monitoring and evaluation. Despite of the existing policy, an implementation plan does not exist. Corruption in drug supply and registration and reduced access to essential medicines, including ORS, zinc, amoxicillin and ACTs exists in both public and private sector. The Drug Control Organization or a control body should be set at national level to survey and scientifically forecast the availability, distribution, procurement and sales for medicines (ORS, zinc, amoxicillin), as well as take into account the seasonal and demographic variability in the demand of these medicines. Proper storage facilities don't exist at the national level and because of which drugs are destroyed and not adequately stored. GDP certified warehouses need to be built and lists of these should be available with the public facilities. Drug procurement reforms centered on electronic bidding will have to be introduced and phased-in for enhancing transparency. A Real-Time Inventory Management System can be designed to ensure effective management and monitoring of medicine consumption in health facilities.

Over burdening of LHWs and lack of awareness regarding recognition of signs for pneumonia and zinc's role in diarrhea management also contributes as a barrier to access of proper medicines. Hiring more LHWs, providing them with regular refresher courses and rapid diagnostic tools and assigning LHWs with specific responsibilities can help increase the effectiveness of their performance. Providing them with incentives such as pay per performance after regular evaluations to see if the area they cover show positive trends, can encourage them to perform more effectively. There also needs to be a strict evaluation and monitoring of the LHW system.

In Pakistan, mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses and paramedical staff. More than 70% of care givers seek help from GPs. Unfortunately, knowledge of GPs regarding the recognition of important signs for pneumonia and appropriate management for pneumonia, diarrhea and malaria is lacking. Continued Medical Education (CME) seminars and workshops emphasizing on these three illness and the guidelines for their management can help in influencing GPs in providing appropriate management. GPs who participate in CME seminars would be provided with accreditation. Some level of training regarding the appropriate use of essential medicines can also be provided to chemists since care givers often directly refer to chemists for medicines.

The effectiveness of "Diarrhea Package" (comprising low osmolality ORS, Zinc, water purification tablets and pictorial instruction sheet in a single pack) has been tested in a trial and it was found that that Diarrhea Pack is acceptable in the community. It has also been found that diarrhea pack can substantially reduce diarrhea burden and cost. The intervention has full potential to be scaled up at National level through the LHWs National programme.

In Pakistan 63% of the total drug expenditure is borne by households, so financial schemes can be designed to ensure patient compliance with therapy and protect households against this catastrophic expenditure.

PROPOSED INTERVENTIONS			
1) Drug Management	2) Scaling Up Community Programs		
Central Body for Drug Control	Revision of LHW Curriculum		
Quality Control	Provision of appropriate diagnostic tools		
Post Marketing Survey	Distribution of work		
Introducing New Vaccines	Incentives or Pay-on-performance		
Monitoring and Evaluation	Up gradation of Referral facilities		
3) Partnering with Pharmaceutical Industry	4) Advocacy and Demand Generation		
Price regulation and rational selection	Mass Media		
Meet Demand	Marketing Campaigns		
Improving coverage and access	Collaborating with producers of FMGs		
Introduction of "Diarrhea Management Pack"	Community Education		
5) Warehouse and Logistics	6) Educate GPs and chemists		
Building Warehouses	CME seminars and workshops		
Real-Time Inventory Management System	Training Chemists		
Electronic Bidding	Regular monitoring		
7) Financial schemes			

BACKGROUND

The Islamic Republic of Pakistan is a geographically diverse country spanning over 796,095 sq. km, encompassing snow covered peaks of the Himalayas and Karakoram ranges, barren deserts, fertile irrigated plains of the Indus River and costal stretches along the Arabian Sea. Situated in South Asia, Pakistan shares its borders with four neighboring countries— Iran to the west, Afghanistan to the north-west, the People's Republic of China to the north and India to the east. Pakistan is rich in ethnic and culturally diversity. Pakistan is the sixth most populous country with a population of 175,867,987, and growing at roughly 1.6 percent per annum.¹Much of the population resides in rural areas; however rapid urbanization has led to the emergence of megacities resulting in dramatic social changes. As of 2010, 37% of the population lives in urban centers, growing at an annual rate of 3.1%.² Geographically, the country is divided into four provinces: Punjab, Sindh, Baluchistan and Khyber Pakhtunkhwa. The provinces are divided into 105 districts called zillahs, which are further divided into Tehsils. Tehsils may contain villages or municipalities.

Pakistan is modeled as a three branched federal republic. The Executive Branch of the government consists of a chief of staff, prime minister and cabinet. The Legislative Branch also known as the Majilis-e-Shoora consists of a 100 seat Senate and a 342 seat National Assembly, which reserves seats for women and non-Muslims. The Judicial Branch is divided into a Supreme Court system with justices appointed by the president as well a Federal Islamic or Sharia Court.³Local governance is divided into eight administrative units and four provincial governments.

Pakistan being a developing country has faced multiple challenges ranging from political, social and economical over the course of its history. The domain of health has been no exception. The first Burden of Disease Study for Pakistan was reported in 2000.⁴It showed that an equal burden could be attributable to infectious vs. non-infectious diseases (38.4 % vs. 37.7%), the latter surpassing if the burden of injures (11.4%) is added. However, data from the year 2008 has shown a much greater burden of infectious diseases as compared to non-infectious⁵ Diarrheal diseases rank number three amongst the top causes of mortality in the country and infectious diseases in general are the number one cause of morbidity/ disability.

The MDG Goal 4 "reduce child mortality" focuses on six indicators: under-5 mortality rate, infant mortality rate, proportion of fully-immunized children 12 -23 months of age, proportion of 1 year children immunized against measles, proportion of children under five who have suffered from diarrhea and Lady Health worker coverage of target population.

Pakistan has one of the highest childhood deaths burden in the world. Nearly 465,000 underfive children die each year in Pakistan and one in ten children does not survive till their fifth birthday. Most of these deaths are caused by preventable illnesses. The earliest available data shows that in the period of 1986-'90, the under 5 mortality rate in Pakistan was as high 117 per 1000 (PDHS 1990-91). According to a UNICEF statistic this rate peaked at 130 per 1000 in 1990. However, in subsequent years there has been a steady decline to 92 per 1000 as reported in the 1997-2001 period by the DHS.⁶Since 1997, the rate has fluctuated in the 90's until finally hitting a low of 87 per 1000 in 2009 (UNICEF). Despite this decline, there is still a need to reduce the under-five mortality rate by 42% points by 2015. If the trends observed during the first four years of MDGs could be achieved, it might be possible to achieve the targets by 2015. Presently, the greatest burden of under-five mortality is in the Sindh province with a rate 101 per 1000, followed by Punjab (97 per 1000), Kyber-Pakhtunkhwa (75 per 1000) and lastly the province of Baluchistan with a rate of 59 per 1000.⁶ However, considerable progress has been made since a study reported rates well above 100 per 1000 in all four provinces in 1995-'96, with Baluchistan then having a under-five child mortality rate of 148 per 1000. Studies have also shown consistently that there is a greater burden of under-five deaths among rural regions when compared to urban settings.^{6,7}

The diseases that contribute the most to mortality in children under five and neonates in Pakistan are illustrated in figures (1) and (2). Diarrhea and pneumonia are the top in the list, each being the cause of around 20% of deaths in children under five years of age.



Pakistan has shown considerable progress in infant mortality reductions as well. In the period of 1986-'90, Pakistan Demographic Health Survey found an infant mortality rate of 91 per 1000. Subsequent trends have shown a decrease to a rate of 71 per 1000 in 2009.² According to the MDG report, 2010, these numbers are not very optimistic and need to be further investigated further as to why this indicator, despite lot of efforts, is off-track.⁸With regards to provincial data, Balochistan has seen the greatest improvement in infant mortality reductions, with infant mortality rates as high 117 per 1000 in 19995-'96 and now only 49 per 1000. In the ten year study period of 1996-2006, Kyber-Pakhtunkhwahad an infant mortality rate of 63 per 1000 and both Sindh and Punjab had rates of 81 per 1000.⁹ Similar to trends seen with under-five mortality rates, infant mortality was consistently greater in rural setting than urban centers.⁹

The Demographic Health Survey from 2006-'07 reports that neonatal mortality has been fairly constant over the years around50 per 1000.⁹According to the most recent data in 2006-'07, the

neonatal mortality rate in Pakistan was 54 per 1000. By province, Baluchistan has the least neonatal mortality burden with 30 deaths per 1000, followed by Khyber-Pakhtunkhwa with 41 per 1000, then Sindh with 53 per 1000 and the greatest burden being in Punjab with 58 deaths per 1000.⁹ Variations between places of residence, urban vs. rural, are less demarcated than in under-five mortality and infant mortality rates. In a ten year study period between 1996 and 2006, the DHS reports neonatal mortality rates to be 48 per 1000 in urban residencies as opposed to 55 per 1000 in rural geographies.⁹ (Table 1)





The proportion of children immunized against six preventable diseases shows improvement to 78% in 2008-09 from 53% in 2001-02. These numbers are not very impressive and there is an urgent need to improve the immunization process.⁸ Since its launch, the Lady health Worker's Program is considered to be one of the most successful program in Pakistan's heath sector in terms of providing primary health care services at doorstep in rural areas.⁸ Immunization rates also show that in 2004, 33% of children under 12-months of age did not get immunized against measles and 20% against tuberculosis.¹⁰ Pakistan's performance to achieve the desired targets of MDG 4 by 2015 has been unsatisfactory, particularly in case of under-five mortality rate and infant mortality rate.⁸(Figure 3)

Source: MDG Report – Pakistan, 2010

		•	
Background characteristic	Neonatal mortality	Infant mortality	Under-five mortality
Residence			
Urban	48	66	78
Rural	55	81	100
Province			
Punjab	58	81	97
Sindh	53	81	101
Khyber	41	63	75
Pakhtunkhwa			
Baluchistan	30	49	59
Wealth quintile			
Lowest	63	94	121
Second	60	87	102
Middle	52	74	90
Fourth	47	67	79
Highest	38	53	60
Source: Pakistan D	HS 2006-07		

Table 1: Early childhood mortality rates

Even though the prevalence of both diarrhea and pneumonia amongst under-five children is high in the country, a relatively low proportion of children receive appropriate treatment. Only 37% of children suffering from diarrhea are appropriately treated with Oral Rehydration therapy⁶ and only 2.8% receive zinc appropriately (table 2).¹¹Moreover, only about half of the children suffering from pneumonia receive an appropriate antibiotic.⁶ 20.1% of children suffering from diarrhea 31% receive no treatment for pneumonia.⁶

Disease	Child Deaths (under five)	Percentage of total child deaths	Proportion Receiving Appropriate Treatment	Proportion of untreated cases per year
Malaria	0.8 per 100,000	1%	3%	
Pneumonia	91,000	14%	50%	31%
Diarrhea	53,300	19%	37% (ORT) 2.8% (Zinc)	20.9%

This highlights the burden of diarrhea, pneumonia and malaria in Pakistan and an urgent need to find efficient ways to address them. Preventing these illnesses holds its importance but treating them accurately and timely has its significance. We in this review would analyze the barriers which are hindering the correct treatment with a special focus on provision of essential medicines and finding ways to scaling up their availability and augmenting use.

HEALTH CARE SYSTEM IN PAKISTAN

The health system in Pakistan consists of public and private sectors. The private sector provides health services to 70% of the population, whereas the public sector covers the remaining 30%.

The total annual expenditure on health in Pakistan in 2008 was PKR.299,651million which is 2.9% of the total GDP. The annual expenditure on health per capita was PKR 1,828 (US\$ 24). Out of the total expenditure on health, government accounts for 29.7%, while the private health expenditure covers the remaining 70.3%.

In Pakistan, there is an existent system for public health services like public health insurance, social insurance and other sickness fund that provides at least partial coverage for medicines that are on the Essential Medicines List (EML) for inpatients and outpatients.

Sales of medicines in Pakistan are regulated by the Drugs Control Organization, Ministry of Health, which requires the registration of all drugs, licensing of pharmaceutical units and also develops the National List of Essential Medicines.



Figure 4: Health care structure.

Source: Health profile Pakistan – WHO, 2006

Public sector landscape

The public sector was until recently led by the Federal Ministry of Health, however the Ministry was abolished in June 2011 and all health responsibilities (mainly planning and fund allocation) were devolved to Provincial Health Departments which had until now been the main implementers of public sector health programs. The amendment has granted provinces greater autonomy, and has devolved decision making in many sectors including health. In principle, devolution of powers can improve governance and has the potential to improve health equity. However, it is vital that national health matters are identified, and related responsibilities are entrusted to a federal institution. There are many national responsibilities for health in federal systems, including health information, regulation, international commitments, trade in health,

establishment of policy norms and standards, and interprovincial policy coordination. These responsibilities have to be centrally managed as in other developed nations.¹²

There are many other areas where central coordination on behalf of the provinces even in the scenario of enhanced provincial autonomy can spare provinces from unnecessary duplicative work for which they neither have human resource capacity nor the institutional arrangements in place. Other than normative functions, economic coordination with donors and bulk procurement of medicine and supplies where cost saving can be achieved, and medicines and human resource regulation fall in this space. Currently most arrangements, the Central Licensing Board, Drug Regulatory Board and the Drug Appellate Board exist at the federal level whilst Quality Control Boards exist at the provincial level. It would be an unnecessary duplication to try and recreate the former category, provincially¹³

Public health delivery system functions as an integrated health complex that is administratively managed at a district level.¹⁴ The state provides healthcare through a three-tiered healthcare delivery system and a range of public health interventions. The former includes Basic Health Units (BHUs) and Rural Health Centers (RHCs), forming the core of the primary healthcare structure. Secondary care including first and second referral facilities providing acute, ambulatory and inpatient care is provided through Tehsil/taluka Headquarter Hospitals (THQs), and District Headquarter Hospitals (DHQs) which are supported by tertiary care from teaching hospitals. Maternal and Child Health Centers (MCHCs) are also a part of the integrated health system; however, the number of MCHC remains limited.¹⁴



Figure 5: Organization of the public health system

The vast majority of rural households are more than 10 kilometers from the district headquarters, ambulance services, ultrasound services for pregnant women, a functioning maternal and child health center, and a hospital.¹⁴ The distance from the health center has even been a disincentive to seek care especially in case of women who would need somebody to accompany them. The distance factor gets strongly adhered to other factors such as availability of transport, total cost of one round trip and women's restricted mobility.

Private sector landscape

Amongst those who seek treatment for diarrhea, around 21% seek treatment from the public sector, where as 77% seek treatment from the private sector.¹⁵ Pakistan's private health sector system consists of 972 hospitals with a total of 104,137 hospital beds, 4,842 dispensaries and 5,344 basic health units (BHUs) mostly in rural areas. In 2007, the Government of Pakistan reported that there is one hospital available for over 170,000 persons, one rural health center available for more than 184,000 persons living in rural areas; one basic health unit available for more than 19,000 persons in rural areas; and one maternal and child health center available for more than 4,400 expecting mother and newborns.^{14, 16}

DRUG REGULATION AND LOGISTICS

Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the constitution.¹⁷ 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. The question of policy norms related to the three levels of regulation—quality, price and Intellectual Property Rights (IPR) regulation—is deeply related to the functioning of Drug regulatory Agency of Pakistan (DRAP). Currently, the Drug Policy 1997 and Drug Act 1976 are in force, but many weaknesses exist. The drug rules are exploitable, particularly in relation to warranty of drug sale, Nutritional and traditional medicines, prescribed by 130,000 practitioners of traditional medicine and devices and related healthcare technologies are outside of the drug act's purview. Policy norms lag behind in relation to trends in technology, advertising and WTO agreements. There is need for a predictable and transparent pricing policy related to branded and generic medicines. These considerations call for updating norms and eliminating room for maneuvering.¹⁸

Pakistan meets 70% of its domestic demand of medicines from local production and 30% through imports.¹⁹ Although at the time of independence in 1947, there was hardly any pharmaceutical industry in the country there are currently 30 multinational and 411 local units involved in pharmaceutical manufacturing.¹⁹In Pakistan, there are legal provisions for controlling the pharmaceutical market. The total pharmaceutical expenditure in Pakistan for 2007 was PKR 12,000 million (US\$ 1,844 million). The pharmaceutical expenditure per capita was PKR 683.²⁰The annual growth rate of the generic pharmaceuticals market value in 2009 was 20%.²¹ National drug Policy exists in Pakistan but is not regularly monitored which covers selection of essential medicines medicines pricing, procurement, distribution, regulation, pharmacovigilance, rational use of medicines, human resource development, research, monitoring and evaluation and traditional medicine. Despite of the existing policy, implementation plan does not exist.

There is an existing system also present for the check and balance of drug quality and market control. Elaborate regulatory arrangements exist even today at the federal and provincial levels. The real issue is at the level of capacity and transparency. Inspectors are poorly paid resulting in 'subsistence corruption'. The numbers are paltry— 250 for a population of 170 million. Drugtesting laboratories are few. Less than 2000 out of the 50,000 retail outlets employ qualified

pharmacists while all the universities put together train less than 2000 pharmacists per year. Sale and resale of second-hand machinery is unregulated, raw materials are traded in the open market, tariff collusion is rampant, hospitality-based incentive-intense marketing practices are endemic and back street manufacturing and spurious drugs continue to burgeon.¹⁸ Laboratory exists in Pakistan for quality control testing. Samples are collected by government inspectors for undertaking post-marketing surveillance testing. In the past 2 years, 60,000 samples were taken for quality control testing. 1,194 of the samples tested failed to meet the quality standards. The results are not publicly available.²²

The government supply system department in Pakistan does not have a Central Medical Store at National Level, but stores exist at district level. There are national guidelines on Good Distribution Practices (GDP). There is a licensing authority that issues GDP licenses. The licensing authority does accredit public distribution facilities. Lists of GDP certified warehouses and distributors do not exist in the public sector.^{23, 24}

Procurement of drugs is based on an essential list of medicines specific for each facility tier; however procurement in practice has also frequently involved purchasing of other drugs not on the list. Although a computerized Health Management Information System (HMIS) exists there is little link between case volume and morbidity generated by HMIS reports and the process of forecasting and budgeting. Purchasing is done on the basis of cheapest tender submitted by any licensed drug production company. This has often been criticized as it results in low quality threshold as company registration is used as the only quality criteria and with the presence of 500-650 licensed production companies in Pakistan, it does not serve to discriminate on quality aspects. The onwards supply chain essentially relies on manual record keeping and although a computerized drug logistics management systems is in place for the GFATM it is yet to be applied to the public sector. Existing public sector procurement practice has resulted in curtailing drug expenditure. A median price ratio (MPR) compares local price to international price and a MPR of greater than 2.5 indicates excessive medicine prices. Generics purchased by public sector are either below or equal to the international price index however branded drugs have been bought up to 3.5 times the international reference prices.²⁵ The price index of public sector, for both generics and branded drugs, is more efficient than that of the private sector in Pakistan. Whether efficiency has been achieved as a result of quality compromise, needs serious exploration. In Pakistan basic generic medicines in private retail outlets have a MPR range of 1.2-7.3 and originator brands for basic therapy have a range between 0.8-15.8.²⁵ The government runs an active national medicines price monitoring system for retail prices. Regulations exist mandating that retail medicine price information should be publicly accessible. The information is made publically available through the Official Gazette Notification.

Counterfeit medicines constitute between 40-50% of total supply in Nigeria and Pakistan.²⁶ Counterfeit medicines result in either under-dosage or even active harm causing injury or death. It also undermines the incentives of registered pharmaceutical producers to invest in quality control. At the same time the gap between generics and originator brands is extremely high and needs to be reduced through both price regulation and rational selection. Anecdotal evidence highlights institutionalized malpractices in procurements where standard mark-ups are charged as a result of collusion between public entities and production companies.²⁷ Procurement has traditionally been done at the provincial level with supply onwards to different districts however as a result of devolution to district level under the Local Governance Ordinance of 2001 drug budgeting, procurement and management took place at the district level for a stretch of nearly ten years. With lapse of the ordinance in 2010, it is uncertain whether there will be a shift back to centralized procurement and supply. As yet there has been no study to assess the relative performance of district versus provincial based drug management.

A survey of first level care facilities, district hospitals and tertiary hospitals conducted as part of Emergency Drug Supply Project in NWFP, Punjab and Balochistan, highlighted issues related to drug storage and dispensation.^{28, 29} Dispensing time on average was merely half a minute which is inadequate for good dispensing while communication with patients was poor and is a cause for concern given low awareness level of patients. Preparation of prescriptions by dispensers is often unhygienic, prone to mistakes and every one in five prescription is dispensed without validation. Preparation, labeling and record keeping of drugs were also inadequate. Storage issues were also examined at public sector facilities. It was found that while stock auditing was satisfactory at majority of sites, presence of essential drug list was seen in only one facility, storage conditions including temperature maintenance, hygiene and pest control were unsatisfactory at majority of places, and actual store capacity was not known by 97% of storekeepers. Store keepers lacked both pre-service and in-service training on proper stock handling. Another study reports labeling and storage of anesthetic medications across 58 operation rooms. Only 15% of operating rooms were compliant with proper drug labeling.²⁹

In Pakistan, mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses and paramedical staff.³⁰ Many drug sellers have minimal formal education and little or no professional training; of those with training, most are absent from pharmacies³¹ a practice also observed in other developing countries. While there are regulatory checks on drug quality at retail outlets there is little regulation of quality of retail outlet. A cross-sectional survey of 311 pharmacies /medical stores in Rawalpindi showed that the proportion of pharmacies meeting licensing requirements was only 19.3% [95% C.I: 15.1, 24.2].³² Qualified staff was present in only 22% of pharmacies. Only 10% had a temperature monitoring device and only 4% had an alternative power supply for refrigerators as a back-up for frequent power outages. A study in Karachi revealed that only 11% of pharmacies in Karachi have a visible license and only 12% are pharmacologically trained.¹²

Availability of even essential recommended generics is extremely low in public sector facilities with a 3.3.% median availability and is much lower than the range of 29-54% found in LMICs while originator brand medicines are generally not available in public sector facilities in Pakistan as well as other LMICs.²⁵. Availability of medicines for acute care range between 30-67% while availability of essential chronic care drugs for management of cardiovascular disease, diabetes, chronic respiratory disease, glaucoma and palliative cancer therapy ranges between 3-57%.^{25, 33}

The Government of Pakistan launched a country wide program known as the People's Primary Healthcare Initiative (PPHI) involving contracting the management of BHUs for improved service

delivery. Out-sourcing of BHUs has been done to the National Rural Support Program (NRSP) and the initiative is administratively housed under and financially assisted by the Federal Ministry of Industries. It is an example of contracting-in through management contracts and involves outsourcing the operation budget of BHUs by the department of health to the contractor accompanied with financial and administrative powers for flexible usage of budget and staffing to improve BHU utilization. Overall,2391 BHUs and 701 other health facilities including dispensaries and MCH centers have been contracted out over 127 districts including 36 in Punjab, 23 Sindh, 30 in Balochistan, 31 in NWFP and 7 in Gilgit-Baltistan. Further experiments with alternative financing models are underway with performance based contracting out, contracting in and competitive voucher schemes being rolled out in the province of Sindh with Norwegian government and one with UN Program assistance.

A study to evaluate the pilot of BHU contracting in Rahim Yar district of Pakistan was conducted using intervention and control districts. Although it found mixed result with improvements in curative care and under performance in preventive and promotive care, drug availability was improved in contracted BHUs. Users reported 30% availability of medicines in contracted BHUs as compared to only 7% in non-contracted.³⁴

CROSS DISEASE BARRIERS

In Pakistan, political instability and corruption in public health care systems is a major obstacle to the effective implementation of national disease control programs. Lady Health Workers, general practitioners and pediatricians are not well-trained to identify important signs for pneumonia and diarrhea in children. Moreover, there are widespread "quacks" and unlicensed health care providers across the country, especially in the less privileged areas that are providing unregistered medicines. Even doctors who are well-trained spend less time in consultations and do not explain the treatment properly.

Care givers are not aware of the signs that should prompt them to seek treatment from a health facility. Cultural misconceptions amongst care givers are also a hindrance in seeking appropriate care. Diarrhea and ARI are viewed as the influence of super-natural forces as a result of which many people do not access health care settings for proper management and treatment; rather they access folk sector or transpersonal healers for treatment purposes. Mothers also frequently change healers due to over-expectations of treatment outcomes. In addition, GPs in 76.5% of patient encounters dispense drug formulations of unknown composition, commonly known as 'mixtures', made in their own drug dispensing corner, a practice which is not open to monitoring and needs to be actively discouraged.

DIARRHEA

The burden of diarrhea diseases in Pakistan represents a significant but, with proper treatment, surmountable challenge. Trends show that the burden of diarrheal disease amongst children in Pakistan has increased over the years, with a higher prevalence in rural areas as compared to the urban ones (Table 3).⁶ Amongst the provinces, the highest prevalence is in Punjab and Sindh while lowest in Baluchistan.⁶

Table 3: Trends in prevalence of diarrhea in Pakistan

Year	1990-91 (DHS)	1995-96	2006-07(DHS)	2010-11 (NNS)
Total	14.5	18.9	21.8	22.3
Urban	15.0	16.7	21.1	23.2
Rural	14.3	21.0	22.1	22.0
Province				
Punjab	14.4	22.8	20.6	28.5
Sindh	19.6	14.5	23.6	23.4
NWFP	9.6	18.3	24.7	4.3
Baluchistan	8.3	13.9	16.2	12.9

According to data reported by Arif, in 1995-'96 approximately 8.5% of childhood deaths were attributable to diarrheal diseases. The WHO reports that during 2000-03, diarrheal disease was the principal cause of death in 14% of childhood mortality cases. And as of 2007, the burden of mortality from diarrheal diseases made 17.7% of all childhood deaths.

Rotavirus is the leading cause of acute diarrheal episodes, as well as the primary culprit to an estimated 40% of all hospital admissions due to diarrhea in under-five, worldwide.¹⁴ In Pakistan, the incidence of rotavirus infection in children less than 5 years of age is 5.7-8.1 per thousand children, which is lower than that in developing countries and is mostly detected in infants and children less than 2 years of age.^{14, 35} The most common strains of rotavirus in Pakistan are G9P (15%), G1P (13%) and G1 (8.4%). Phan et al. confirmed the presence of Astrovirus, Norovirus (GI, GII), Sapovirus as causes of viral diarrhea, other than rotavirus in children in Karachi, Pakistan.¹⁵ Amongst bacteria, species of the family Enterobacteriaceae are the most common agents associated with diarrhea. It consists of a large, heterogeneous group of gramnegative rods amongst which species of E. Coli, Salmonella and Shigella are the most common causative agents. Strains of pathogenic E. Coli are found to be the most common amongst the bacterial causes of diarrhea in Pakistani children.¹⁶ Campylobacter Jejuni also has an increased incidence rate amongst all age groups in the country due to a high presence of Campylobacter organisms in food commodities used by the common man.

Oral rehydration therapy for diarrhea, the miracle discovery of the 1960s, is perhaps the single best intervention that is both curative and preventive Trends have shown that the global coverage of ORS has not increased since 1995 and is still less than 40%. In Pakistan, the use of ORS in under five children has been declining and currently only 37% children are given ORS for treatment of diarrhea.⁶





Access to diarrhea treatment

Diarrhea prevalence amongst under-five in the country as per DHS 2006-07 is around 21.8% with a mortality of 53,300. The Millennium Development Goal 4 aims to reduce this prevalence to less than 10% by 2015.

20.9% of children suffering from diarrhea receive no treatment. On average, 37% receive ORS, whereas only 2.8% receive zinc.¹¹ 50% were given an anti-microbial while 10% an anti-diarrheal for diarrhea treatment. Amongst those who use ORS, 20.9% obtain it through Lady Health Care workers, 7.9% from private health centers, 67% from private pharmacies and 3.4% from government health facilities. (POUZN report).¹¹

The standard World Health Organization guidelines for diarrhea management recommend:

- Oral Rehydration therapy with low osmolarity oral rehydration salt and zinc (Glucose:20g/Sachet, Sodium Chloride:3.5g/Sachet, Potassium Chloride:1.5g/Sachet, Sodium Citrate:2.9g/Sachet
- Zinc (10-20mg) for 10 days: give 20mg / day for children aged 6 months to 5 years; 10mg/ day for children aged less than 6 months

Both ORS and Zinc are available over the counter in Pakistan and both are included in the Essential Medicines List of Pakistan, 2007.

ORS

The Control of Diarrheal Diseases Programme (CDD) was initiated in 1980s and laid emphasis on the prompt recognition of dehydration, the correct preparation and use of ORS, continued breastfeeding, proper feeding practices during and after diarrhea and improved hygienic practices. The National Commission for Human Development launched an ORS campaign with the objective of training at least one woman in each household regarding preparation and use of ORS. Through this campaign, NCHD trained almost 13 million women in 80 districts of Pakistan. ORS is typically available as packages of 20 sachets, with each sachet costing around Rs. 5-7 (US\$0.08-0.12) on average and are widely available in both sectors throughout the country.¹¹ Though 91% of mothers have heard about ORS,³⁶ only about 2.5% of homes have ORS available.³⁷ 56% of mothers believe that ORS is the best way to prevent dehydration. These figures show the existence of a possible knowledge-accessibility barrier. The table below shows the ORS manufacturers available in Pakistan:

ORS (Powder)		
Trade Name	Company	Price/Sachet (PKR)
Arosal	Alliance	
Babysalt	Polyfine	5.50
Baby-s	Saydon	5.40
Dirosal	Bloom	5.10
Durasal	Drug	6.10
Geofman SP Salt	Geofman	7.30
Hydrolyte	Mendoza	5.5
Kemytral	Alkemy	5.15
Merisole	Miracle	5.0
Orasal-F	Wilson 's	7.0
Oral Rehydration Salt	Frontier	
Orsigen	Genera	6.0
Osmolar	Atco	6.0
Osmoless	Genera	5.0
Paeditol	Wise	7.35
Paeditrex ORS	Helicon	6.5
Pediawin	Jinnah	5.0
Pedisal ORS	Sharex	7.35
Peditral	Searle	10
Ralyte	Dr. Raza	5.4
Rehydrate	Wise	5.0
Safelyte O.R.S	Heal	5.0
Scots ORS	Scotmann	6.0
Sodalite	Macquin 's	
Teknosol	Technovision	6.5
Valosal	Valor	6.0
Werisol	Werrick	7.5

Table 4: ORS manufacturers in Pakistan

Zinc

Zinc is available in both tablets and syrup formulations. 95.8% use the syrup form.¹¹pediatric zinc diarrhea treatment products Is produced locally by four Pakistani pharmaceutical manufacturers including ATCO Laboratories, ZAFA Pharmaceuticals, GenixPharma and Macter International. These products are registered for sale in Pakistan by the Pakistan drug regulatory authority and were tested by the Government of Pakistan pharmaceutical laboratory for quality. These products sell for PKR 35 – PKR 150 (US\$0.41-\$1.76), depending upon the brand and dosage strength.¹¹ A number of other pharmaceutical companies produce zinc products, but these are primarily nutritional supplements rather than for diarrhea treatment. Table below shows the zinc manufacturers available in Pakistan.

Trade Name	Company	Price (PKR)
CNIZ	Genix	60
DELUX-ZINC	Delux	59
E-ZINC	Woodwards	64
MELBEK	Wilshire	50
OK-ZINC	Fynk	75
OPTIZINC	Idress	75
PEDISAFE	NovaMed	50
PROZINK	Hansel	50
YES 2 ZINC	Zafa	45
ZINCASA	Macter	35
ZINCAT	Atco	60
ZINKROL	Lisko	45
ZINCOR	Genome	60
ZING	Nexus	60
ZINKIN	Semos	75
ZINKITT	Lowitt	75
ZYNQ	Nabiqasim	
ZINCOB	Bio-lab	
DIAZINC	Searle	

Table 5: Zinc manufacturers in Pakistan

ZinCat brand of ATCO laboratories is the most commonly used which is available in both tablet and syrup formulations. On average, zinc sulphate packaged as 60 ml. bottle costs around Rs. 4. Tablets are available as packages of 10 tablets and each tablet costs around Rs 5.

A vast majority of caretakers obtain zinc through purchasing (75%) while the remaining 25% obtain it free of cost. The mean price paid for zinc products reported by care givers is 60±8.5. 26.1% of mothers believe that the zinc is affordable and 17.4% of mothers are of the opinion that it is expensive.¹¹ On inquiring whether they would continue to buy Zinc products if the price increased by 50 percent, 55% responded in affirmation.¹¹

Most mothers obtain zinc from private pharmacies (62.7%) or lady health workers (21%); whereas some mothers obtain it from government health facilities (17%).¹¹ The reasons mothers reported for using zinc for diarrhea treatment included: prescription by the health provider (37%), easy accessibility (17%), good quality product (30%) and affordability (13%). Most mothers have reported that they do not have a shop nearby their homes that has zinc available. 30% of mothers do not know where they can get zinc from (POUZN report 2011).

As mentioned earlier, only 2.8% of children under five suffering from diarrhea receive zinc.¹¹Only 10.7% of mothers that use zinc, give it to their child for complete 10 days. Amongst those receiving zinc, only 58% are given ORS along with zinc. Most mothers who do not use ORS with zinc did not know whether ORS should be given with or without zinc.¹¹ Only 3% of mothers have reported that they had heard a message or received information regarding zinc for diarrhea 3 months prior to the survey. 50% of those who received messages/information regarding its use, had heard it through a lady health worker.¹¹

	ORS	Zinc
Source of obtaining OBS/7ing		
Source of obtaining ORS/Zinc		
Government Health Facility Private Health Centre LHW Private Pharmacy Traditional healer Don't know Community distributor	3.4% 7.9% 20.9% 67.0% 0.2% 0.6%	7.4% 60% 32.7% - 1.8% 7.3%
		-
Percentage of mothers who have heard about ORS ¹¹	91%	
Percentage of homes with ORS available at home ¹¹	2.5%	
Percentage of mothers who believe ORS is the best way to prevent dehydration ¹¹	56% (knowledge- practice gap)	
Willingness to pay for zinc products		Yes: 55.6%,
If price increased to (amount paid	-	don't know: 16.7%
If price increased to (amount paid		No: 100%
If the price increased to (amount paid		Yes: 90%
Maximum price willing to pay for zinc, mean+-std (Pakistani rupee) Mothers' opinion about the price		63±65.6
of zinc	4 3%	
affordable	26.1%	
expensive	17.4%	
too expensive	13%	
don't know	4.3% 34.8%	
Use of zinc for complete 10 days	10.9%	

Table 6: Care-giver knowledge, attitude and practices towards diarrhea treatment in Pakistan.

Source: POUZN report 2011

According to in-depth interviews with physicians, flagyl is widely known as a diarrhea treatment and often requested by caregivers or pharmacists, without a prescription. ORS plus flagyl is the current standard treatment recommended by most providers.³⁸

Diarrhea treatment barriers

Though 91% of mothers in Pakistan have heard about ORS and 56% believe that it is the best treatment for dehydration due to diarrhea; only 2.5% of mothers have ORS available in their homes. These figures reflect the existence of a knowledge-practice gap amongst mothers for the use of ORS. A survey in Karachi revealed that 76% of pharmacies had pharmacists who did not have the knowledge regarding the current frequency of ORS administration.

Only 2.8% of mothers utilize zinc for the treatment of diarrhea and amongst these, only around 58% use ORS along with zinc since most of them who use zinc are not aware that ORS and

zinc need to be given together. Moreover, they do not give zinc for complete duration of ten days because of difficulty in remembering to give it to the child once diarrhea settles. Mothers are not willing to pay for the current price of zinc since they are not aware of the cost-effectiveness of zinc for treating diarrhea and preventing future episodes of diarrheal illness.

Information sources for zinc's role in diarrhea treatment are also very limited and only around 5% of mothers reported that they had heard a message or received information about zinc in the past 3 months. Mothers are also unsure as to where they can obtain zinc from. Around 41% of mothers reported that they do not have a shop nearby that has zinc available and 30% did not have zinc available at walking distance from their homes.

A study showed that infants were self-medicated particularly during diarrheal episodes, which is a dangerous trend as improper management of childhood diarrhea is the penultimate cause of death in children under five.³⁹General practitioners were also found to prescribe anti-diarrheals more frequently than doctors working in the public sector (p < 0.01).⁴⁰

 Demand Side Lack of awareness regarding the cost-effectiveness of zinc for diarrhea treatment Knowledge-usage gap for ORS Lack of information sources regarding zinc and ORS for diarrhea treatment Unavailability of zinc for sale at shops nearby home Unwillingness to pay for the current price of zinc Lack of awareness regarding the effectiveness of zinc in reducing diarrheal severity Misconception regarding antibiotics being more effective than zinc and ORS for treatment of diarrhea Difficulty in remembering to give zinc for complete 10 days once diarrhea has settled No national line of action on communication and social 	 Public sector Lack of awareness and prescription practices for zinc amongst lady health workers Unavailability of zinc at government health facilities Lack of public efforts to increase awareness amongst caregivers regarding appropriate diarrhea treatment The vaccine for rotavirus, which is the most common cause of diarrhea in Pakistan, is not a part of EPI. Lack of coordination among govt and pharmaceutical industry regarding production of zinc Poor regulatory mechanisms regarding osmolarity of ORS 	 Private sector Around 50% of general practitioners and pediatricians prescribe antimicrobials for diarrhea Most private practitioners are not aware of the inclusion of zinc with ORS for treatment of diarrhea Differences between self-reported and prescribing practices of GPs and pediatricians for diarrhea¹²
 No national line of action on communication and social mobilization 		

Table 7: Diarrhea Treatment Barriers

PNEUMONIA

Globally, around 2 million children die of pneumonia each year and currently pneumonia accounts for 18% of annual deaths in children under five globally, 99% of these deaths occur in developing countries.^{41, 42} Pneumonia remains the leading cause of death in children under 5 years in low and middle income countries despite the introduction of case management guidelines and the development of new preventative strategies including effective vaccines.² 74% of new pneumonia cases occur in just 15 countries and more than half in just 6 countries: India, China, Pakistan, Bangladesh, Indonesia and Nigeria.⁴³ Around 91,000 children under-five

years of age die each year from pneumonia in Pakistan. It contributes to 14% of deaths in under-five aged children of the country.⁴⁴

Table 8 shows the trends in prevalence of ARI in Pakistan. One in six children (16 %) had suffered from symptoms of ARI during the two weeks preceding the DHS 1990-91 survey. ARI symptoms were least prevalent (8 %) in Balochistan, while the highest prevalence was observed in Punjab and Sindh. 14 % of children under age five had symptoms of ARI in the two weeks preceding the DHS 2006-07 survey. ARI symptoms were less evident among children whose mothers had secondary or more education.

Year	DHS 1990-91	DHS 2006-07
Total	16.0	14.1
Urban	13.8	12.8
Rural	17.0	14.6
Province		
Punjab	17.0	13.0
Sindh	17.2	17.0
KP	12.2	16.5
Baluchistan	8.3	3.1

Table 8: Trends in prevalence rate (%) of ARI

In 1989 the government of Pakistan launched the National ARI Control Program, with the primary objective of reducing mortality from pneumonia in under-5-year-olds and of rationalizing the use of drugs in ARI case management.⁴⁵As part of this programme, the standardized ARI case management approach recommended by WHO for the control of ARI, was adopted and modified to meet local needs. Doctors and health care providers were trained with this new technique.⁴⁶ This modified strategy was based on the assessment of clinical signs in children presenting with a cough or difficult breathing: fast breathing, indrawing of lower chest wall, and other specified danger signs.

Antibiotics are recommended for treatment of pneumonia. A study on the impact of the new treatment guidelines at the Islamabad Children's Hospital from 1990-92 revealed that death rates among children admitted to hospital with severe pneumonia fell from about 10% in 1989 to about 5% in 1992. Meanwhile the rational use of drugs, a key strategy in preventing the overuse of antibiotics and curbing microbial resistance, led to a major reduction in the use of antibiotics (from 56% of cases in 1989 to only 30% in 1992).⁴⁷

The current WHO guidelines for pneumonia recommend that for children 2 months to 5 years of age with non-severe pneumonia, five days of antibiotic therapy with either amoxicillin or cotrimoxazole should be used. Children with wheeze and fast breathing and/or lower chest indrawing should be given a trial of rapid acting inhaled bronchodilator, before they are classified as having pneumonia and prescribed antibiotics.

Access to pneumonia treatment

According to DHS 2006-07, prevalence of pneumonia in the country was around 14.4%.⁶ The estimated mortality rate per 10,000 is 48.1.⁴¹ Overall, around 50% of children under five who had symptoms of Acute Respiratory Illness received antibiotics.⁶However 69.9% of children with

suspected pneumonia are taken to a health facility and 31.1% receive no treatment for ARI symptoms.⁶

In 1989, the Government of Pakistan adopted WHO's recommendation of using cotrimoxazole as first-line outpatient treatment for non-severe pneumonia due to its cost, twice-daily dosage schedule, efficacy and bio availability. Changing from cotrimoxazole to amoxicillin would cost an estimated US\$ 25 million; a significant proportion of the national health budget.⁴² A study published in the Bulletin of WHO in 2005 revealed that both standard and double strength cotrimoxazole were equally effective in treating non-severe pneumonia.⁴²

A recent study by Hazir et al. has shown that the clinical outcome in children aged 2-59 months with WHO-defined non-severe pneumonia is not different when treated with amoxicillin or placebo. Further trials are, however, needed to rationalize the use of antibiotics in these communities for non-severe pneumonia.⁴⁴

There are currently no registered amoxicillin tablets in Pakistan that are suitable for children. However, many registered amoxicillin suspensions are available. Most of them are packaged as 60 ml. bottles of amoxicillin 125 mg/5ml. The prices range from Rs.30 to 35 per 60 ml. bottle. Amoxicillin is included in the Essential Medicines List of Pakistan 2007, but Cotrimoxazole isn't. However, both are available over the counter in Pakistan.

Pneumonia treatment barriers

It is expensive to treat children with pneumonia especially as inpatients. In Pakistan, the average cost to treat a child with pneumonia as an outpatient was estimated by activity-based costing as US\$ 13.44, representing 82% of annual health expenditure per person at the time. In comparison, inpatient costs were estimated as US\$ 71 and US\$ 235 for pneumonia and severe pneumonia.

Care givers and health care providers lack awareness regarding the recognition of fast breathing and chest in drawing as important signs for pneumonia. Most mothers seek care from unqualified practitioners who over prescribe antibiotics and are not aware of the WHO guidelines for pneumonia management.

Mothers frequently change healers due to unrealistic expectations of cure. Health care providers do not spend enough time in counseling the mothers regarding the importance of completing the duration of antibiotic and the danger signs that should prompt health seeking.

The National ARI Control Program was launched by the government in 1989 with the primary objective of reducing mortality from pneumonia in under-5-year-olds and of rationalizing the use of drugs in ARI case management. Appropriate monitoring and evaluation of the impact of the ARI control programme is lacking. Lack of funding for programmatic activities, lack of coordination with other child survival programs, inadequate training for community health workers and general practitioners in the private sector, lack of public awareness about seeking timely and appropriate care, and insufficient planning and support for ARI programmatic activities at provincial and district levels are major hindrances in decreasing the burden of ARI in the country.

Table 9: Pneumonia Treatment Barriers

Demand side	Public sector ¹⁷	Private sector			
 Delay in care seeking for ARI Half of the children with ARI in rural areas seek help from untrained practitioners Lack of awareness regarding recognition of chest in drawing and rapid breathing as important signs for pneumonia Unrealistic expectations of cure leading to change in physicians and treatment regimen Expensive treatment of pneumonia for inpatients Do not give antibiotic for full duration 	 Lack of appropriate monitoring and evaluation of the impact of the ARI-control program. Inadequate training of lady health workers (LHWs) Insufficient planning and support for ARI programmatic activities at provincial and district levels Lack of funding for programmatic activities Lack of close collaboration between MNCH, EPI and LHW Programme Pneumoccocal vaccine not a part of EPI yet Lack of diagnostic ability and correct prescription No checks on the quality of drugs Availability of drugs 	 Over prescription of antibiotics in children with wheezing and underutilization of bronchodilator Failure of GPs and pediatricians to recognize fast breathing and chest in drawing as signs on pneumonia Incorrect antibiotic prescription 			

MALARIA

Malaria is a deadly mosquito-borne disease, which takes almost one million lives per year and afflicts as many as a half a billion people in 109 countries in Africa, Asia and Latin America.⁷ Malaria was nearly eliminated in Pakistan during the 1960s, but in 1972 it made a massive resurgence. Since then, malaria has remained a major public health threat, as common irrigation practices and monsoon rains create favorable conditions for malaria-transmitting mosquitoes. Pakistan is endemic for malaria, though only 7% of the population lives in areas of high transmission.⁴⁸ Along with other "Category 3" countries (Somalia, Sudan, Yemen, Afghanistan, Djibouti and Pakistan) of the Eastern Mediterranean Region (EMR), malaria accounts for more than 95% of the regional burden.⁴⁹ Figure 7 shows the geographical distribution of malaria in Pakistan. Most of the malaria burden in the country is shared by Baluchistan and Sindh.⁴⁹





Source: WHO Malaria Report - Pakistan 2009

Malaria has a prevalence of around 20% in under five children of Pakistan.⁶ In 2009, more than 24,000 cases were reported in this age group and 47% of the deaths occurred in children under the age of five. While Pakistan uses both indoor residual spraying (IRS) and insecticide-treated nets (ITNs) for malaria prevention, neither is sufficiently addressing the problem. 176.2 million Pakistanis are at risk of contracting malaria, only 240,000 Pakistanis have ITNs and only 327,360 households are protected by IRS.⁶

151 855	24 714
90 834	21 847
100 896	18 812
90 834 100 896	24 7 14 21 847 18 812

Access to malaria treatment

With an annual incidence of 0.8 cases per 1000 under five children and a mortality rate of 0.8 per 100,000 population, malaria contributes to 1% of under-five deaths in the country. Most of the population of Pakistan (<84%) live in areas of low malaria transmission. A total of 4.2 million probable and confirmed malaria cases were reported in 2009, of which only 167,579 cases were confirmed by either microscopy or RDT. Approximately 30% of the confirmed cases were caused by P. falciparum and almost 42% of the confirmed cases originated in Balochistan province.⁴⁹

Nearly 2.3 million full treatment courses of antimalarial medicine per year were delivered during 2007–2009 and approximately 34,900 courses of ACT were delivered in 2009, which is not sufficient to treat all reported Falciparum cases in the public sector.⁵⁰ Malaria diagnosis is free of charge in the public sector since 1961. However, only 3% of children under five with fever receive an antimalarial drug and only 10% of febrile children under 5 years are treated in a public health facility.⁶

The current National Malaria case management guidelines formed by the Directorate of Malaria Control, Ministry of Health, Pakistan recommend the following:

- For uncomplicated malaria, confirmed vivax malaria: chloroquine for 3 days
- For uncomplicated malaria, confirmed as falciparum malaria: Artisunate for 3 days, plus quinine for 7 days.
- For clinical malaria not yet confirmed as vivax or falcipuram: chloroquine for 3 days
- Treatment failure: Sulphadoxine+pyrimethamine
- Severe malaria: quinine
- Sulfadoxine + pyrimethamineis not recommended for children under 5 years of age and women in their first trimester of pregnancy.
- Antimalarial should be given by weight, especially in children
- Primaquine should Not be given to:
 - Patients without microscopic confirmation of vivax.
 - Pregnant women & children under 4 years of age
 - Patients with Glucose-6-Phosphate Dehydrogenase deficiency

Patients who have received complete dose of Artesunate

The National List of Essential Medicines states that for curative treatment, medicines for P. falipuram malaria should be used in combination. Oral artemesinin monotherapies are not registered in the country. The following combinations are included for curative treatment in the EML, 2007:

AMODIAQUINE	Tablet: 153 mg or 200 mg (as hydrochloride).
	* To be used (a) in combination with artesunate 50 mg OR (b)
	may be used alone for the treatment of P.vivax, P.ovale and
	P.malariae infections.
ARTEMETHER	Oily injection: 80 mg/ml in 1-ml ampoule.
	For use in the management of severe malaria.
ARTEMETHER +	Tablet: 20 mg + 120 mg.
LUMEFANTRINE	* Not recommended in the first trimester of pregnancy or in
	children below 5 kg.
ARTESUNATE*	Injection: ampoules, containing 60 mg anhydrous artesunic acid
	with a separate ampoule of 5% sodium bicarbonate solution.
	For use in the management of severe malaria.
	Tablet: 50 mg.
	* To be used in combination with either amodiaquine,
	mefloquine or sulfadoxine + pyrimethamine.
CHLOROQUINE*	Oral liquid: 50 mg (as phosphate or sulfate)/5 ml.
	Tablet: 100 mg; 150 mg (as phosphate or sulfate).
	* For use only for the treatment of P.vivax infection.
DOXYCYCLINE*	Capsule: 100 mg (as hydrochloride).
	Tablet (dispersible): 100 mg (as monohydrate).
	* For use only in combination with quinine.
MEFLOQUINE*	Tablet: 250 mg (as hydrochloride).
	* To be used in combination with artesunate 50 mg.
	Tablet: 7.5 mg; 15 mg (as diphosphate)
PRIMAQUINE*	* Only for use to achieve radical cure of P.vivax and P.ovale
	infections, given for 14 days
QUININE*	Injection: 300 mg quinine hydrochloride/ml in 2-ml ampoule.
	Tablet: 300 mg (quinine sulfate) or 300 mg (quinine bisulfate).
	* For use only in the management of severe malaria, and should be
	used in combination with doxycycline.
SULFADOXINE +	Tablet: 500 mg + 25 mg.
PYRIMETHAMINE*	* Only in combination with artesunate 50 mg.

For prophylaxis, chlorquine, doxycline, mefloquine and proguanil are included in the National EML.

Malaria treatment barriers

Ever since the inception of RBM project in 2001, Malaria Control Programme has made tangible progress in partnership building, policy guidelines for new interventions such as LLINs, RDTs and ACTs, and imposing bans on the production of oral artemisinin montherapies, injection chloroquine and halofantrine, which were injudiciously prescribed by private care providers. WHO has been the major agency providing technical assistance and supporting the programme in its initiatives. However, low technical and managerial capacities of the programme at national and provincial levels and low coverage of interventions of the population at risk are the major challenges faced by the Programme.

Despite the ban on the production of monotherapies, there is still continued high demand and sales of monotherapies. This may be due to the lack of awareness amongst health care providers and care givers regarding the effectiveness of ACTS as the effective treatment for malaria. Moreover, the cost of ACTs is high as compared to monotherapies which leads to non-compliance.

Table 12: Malaria Treatment Barriers								
Demand side	Public sector	Private sector						
 Continued high demand and sales of SP and monotherapies Delayed seeking of health care for febrile children with suspected malaria High cost of ACTs leading to non-compliance 	 Low coverage of National Malaria control Program Weak technical leadership at both federal and provincial level and managerial capacities of the National malaria control program Staffing constraints for the national malaria control program Provincial-level control programmes struggle with phasing out old "eradication" strategies such as active case detection, Inadequate access to rapid diagnosis and prompt treatment in health facilities Lack of monitoring and evaluation in districts where "roll-back malaria" activities have been initiated. Inconsistent reporting on financing by the national government for malaria control efforts Poor Availability of drugs 	 Poor availability and high cost of ACTs in the private sector Lack of awareness regarding recent guidelines for malaria treatment with ACTs instead of monotherapies amongst GPs and pediatricians 						

HEALTH INITIATIVES

The Federal Ministry of Health (MoH) and Provincial Departments of Health (DoH) are implementing a number of initiatives, which focus on addressing the challenges of child health. Key present initiatives related to maternal and child health are:

- National Program for Family Planning and Primary Health care
- National EPI Programme
- Nutrition Project
- MNT-Special Immunization Activities.
- National Program for Control of Diarrheal Diseases (CDD)
- Acute Respiratory Infections Control Project
- Polio Eradication
- Integrated management of childhood illnesses (IMNCI) strategy (1998 ongoing)
- Women's Health Project (in 20 districts)
- Reproductive Health Project
- Baby Friendly Hospital Initiative / Breast Feeding Promotion
- Malaria eradication

- RBM
- Child survival program 1992
- Social action plan 1993
- Maternal, Newborn & Child Health program 2005

Cross Disease initiatives

Immunization

EPI (Expanded Program on Immunization) program is running effectively, with broader but variable coverage in various districts of the country. EPI aims to reduce morbidity and mortality amongst children under 1 year of age, due to vaccine preventable diseases namely Poliomyelitis, Diphtheria, Pertussis, Tuberculosis, Tetanus, Hepatitis & Measles. Hepatitis B has been introduced countrywide in EPI program since 2002. Polio is near eradication because of intense supplementary immunization activities (NIDs and SNIDs) in addition to regular EPI program.

Baby Friendly Hospital Initiative / Breast Feeding Promotion

A UNICEF supported programme of promotion, protection and support of breast-feeding was started through Baby Friendly Hospital Initiative (BFHI) in teaching hospitals and health facilities of the provinces during 1995. It was expanded to district hospitals in the following years. There is no separate budget allocation for breast-feeding promotion, as it is an integral part of health education.

National Program for Control of Diarrheal Diseases (CDD) and Acute Respiratory Infections Control Project

Program to effectively control the Diarrheal diseases and ARI was initiated with the assistance of international agencies. Under this program following activities have been undertaken:

- 1. Development of simplified and specific treatment protocols
- 2. Printing and wide distribution of these protocols
- 3. Training to all level of services providers for better patient management

4. Development / modification of information system for these diseases for better data management.

The Lady Health Worker Program

The National Programme for Family Planning and Primary Health Care in Pakistan (commonly called the Lady Health Workers or the LHW program) was launched in 1994 by the government of Pakistan. Programme objectives contribute to the overall health sector goals of improvement in maternal, newborn & child health; provision of family planning services; and integration of other vertical health promotion programmes. This country wide initiative with community participation constitutes the main thrust of the extension of outreach health services to the rural population and urban slum communities through deployment of over 100,000 Lady Health Workers (LHWs) and covers more than 65% of the target population.

As the largest community based initiative in the country, 'the Lady Health Worker model' is built around the concept of providing easy and continued access to primary health care services at the door steps of the community through women volunteers from the community. The Programme however adopted the model of paying a 'stipend' to the community workers (Lady Health Workers) in order to keep them motivated and for retaining trained human resource. The conceived role of the Lady Health Workers (LHWs) includes helping communities identifying and addressing their health needs on their own as well as serving as a link between communities and the health system. They bridge the gap between the health facility and communities, through provision of quality integrated primary health care services.

The Programme began with strength of a little over 30,000 LHWs and over the years has expanded to a strength of over a 100,000 LHWs currently deployed across all provinces and regions of the country. The Programme coverage extends to more than 65% of the target population which is the rural population and communities living in urban slums across the entire country. The Programme operates in all 135 districts of the country. However within certain districts there are still hard to reach areas where the Programme does not exist. The main constraints for absent Programme coverage are non-functional health facilities or low female literacy with women not meeting the selection criteria for recruitment as LHWs and LHSs.

IMCI

The Integrated Management for Childhood Illnesses (IMCI) strategy was formally endorsed by the Ministry of Health of Pakistan in September 1998 but the early implementation phase completed at district level in October 2000. Two years later, the community component of IMCI was launched and IMCI was introduced in pre-service education on a pilot basis at Nishtar Medical College, Multan in October 2002. In 2003, the project was expanded to two more districts. By 2005, the strategy covered all four provinces, 6% districts, only 2% health facilities and 9% under five aged children of the country. However, by 2010, 70.5% of districts have at least one health facility that has implemented IMCI strategy and the percentage of health facilities that are implementing IMCI rose to 24.4%.⁵¹

Diarrhea Specific Initiatives

To promote the use of oral rehydration therapy (ORT), a training programme was launched by Pakistan National Programme for Control of Diarrheal Disease (CDD) by establishing the Diarrhoea Training Units (DTUs). Physicians trained at DTU were designated to establish functioning oral rehydration therapy (ORT) corners at their health centers and train health workers in delivery of facilities on standard diarrhea case management.⁵² Twenty-four out of 49 ORT corners were non-functional after three years of their establishment, mainly due to frequent transfers of trained staff. In 22 ORT corners evaluated, performance of health professionals was far from satisfactory, 19 out of 22 doctors were found to have inadequate performance in diarrhea management and only 3 out of 7 LHVs performed adequately. LHVs could not consistently deliver health education messages to mothers. There seems to be a lack of interest and willingness to participate actively, as more than 50% of both doctors and LHVs did not consider ORT work as their job.⁵²

Both public and private sectors are working to address diarrhea related needs via their own distribution and promotion channels. In 2009, the Ministry of Health (MOH), working through its own Zinc Technical Advisory Committee, began to focus greater attention on diarrhea through

its Lady Health Worker (LHW) Program. The LHW National Directorate purchased 4.5 million bottles of zinc syrup from local pharmaceutical manufacturers for the 2009 diarrhea season (primarily May through August) providing each LHW with a supply of 5-6 bottles/month for free distribution. In 2010 the MOH's LHW Program again procured 5 million bottles of zinc syrup in order to provide each of their 103,000 LHWs with 8-10 bottles/month (or more as individually required). All LHWs have been trained in management of diarrhea using zinc and it is included in the training curriculum. The MOH also featured oral rehydration salts (ORS) and zinc during its spring 2010 Child Health Week and placed diarrhea management with zinc as one if its two priority best practices (along with birth spacing). At the same time several firms from the Pakistani pharmaceutical industry were developing pediatric zinc products, registering them with regulatory authorities and distributing them through their normal distribution channels.

In January 2009, the USAID Mission to Pakistan invited the Social Marketing Plus for Diarrheal Disease Control: Point-of-Use Disinfection and Zinc Treatment (POUZN) Project, implemented by Abt Associates, to conduct an assessment of the role of the private sector in diarrhea treatment and to present options for supporting private sector firms in their efforts to market and distribute pediatric zinc for diarrhea treatment through both commercial channels and community distribution systems. Based on that assessment, the POUZN project developed a program in Pakistan to support local manufacture of pediatric zinc products with mass media generic advertising and training for providers.

Diarrhea Pack Project was carried out from January 2009 to December 2010 at 8 union councils in Taluka Khairpur and Taluka Pind Dada Khan. ORS, Zinc Tabs, Water purification Tabs and pictorial instruction sheet were packaged into a single pack and were distributed through GPs, pharmacies and LHWs. An evaluation of the impact of the project showed that 94% of participants in the intervention group considered the diarrhea pack to be useful and 93% expressed willingness to pay for it. Further, it is feasible to introduce Diarrhea Pack for the treatment of diarrhea in health systems at scale.

Barriers	Current efforts
Demand side Lack of awareness regarding the cost-effectiveness of zinc for diarrhea treatment Knowledge-usage gap for ORS Lack of information sources regarding zinc and ORS for diarrhea treatment Unavailability of zinc for sale at shops nearby home Unwillingness to pay for the current price of zinc Lack of awareness regarding the effectiveness of zinc in reducing diarrheal severity Misconception regarding antibiotics being more effective than zinc and ORS for treatment of diarrhea	The POUZN project developed in 2009 helped in improving caregiver knowledge and treatment of childhood diarrhea so that caregivers provide ORS together with zinc as the first-line treatment for uncomplicated diarrhea.
Public sector Lack of awareness and prescription practices for zinc amongst lady health workers Unavailability of zinc at government health facilities Lack of public efforts to increase awareness amongst mothers	The Pakistan National Programme for Control of Diarrhoeal Disease (CDD) launched a training program for physicians to promote ORT in 1997.

Table 13: Current efforts for diarrhea

Barriers	Current efforts
regarding appropriate diarrhea treatment	In 2009, the Ministry of Health (MOH), working through its own Zinc Technical Advisory Committee, began to focus greater attention on diarrhea through its Lady Health Worker (LHW) Program Diarrhea pack project (Diarrhea Package, comprising low osmolality ORS, Zinc, water purification tablets and pictorial instruction sheet, distributed through GPs, pharmacies and CHWs in 8 union councils; social marketing of the package
Private sector Most private practitioners are not aware of the inclusion of zinc with ORS for treatment of diarrhea Flood affected areas led to increase outbreaks in diarrhea due to lack of clean water drinking resources	In 2009, the Point-of-Use Disinfection and Zinc Treatment (POUZN) developed a program in Pakistan support local manufacture of pediatric zinc products with mass media generic advertising and training for providers Safe drinking Water Alliance: Centre for disease Control developed PuR- a new water purification technology provided to areas of the country affected by 2010 floods. Funded by USAID (\$1 million), Proctor and Gamble (\$0.5 million

Pneumonia Specific Initiatives

Pakistan is all set to becoming the world's 16th country to introduce the pneumococcal conjugate vaccine for protection of children against pneumonia. The vaccine, will be available as part of free immunization service for children all over the country by March 2012, funds have been secured with the support of the Global Alliance for Vaccines and Immunization (GAVI) against a total cost of 618 million dollars and for a period of five years, with the government of Pakistan bearing only 19 million dollars of the cost.

The National ARI control program was launched in 1989 in Pakistan to reduce childhood mortality from pneumonia. In this programme, peripheral health workers are trained using recognizable signs, such as increased respiratory rate and the presence of chest retractions, to detect pneumonia that requires treatment with antibiotics at home or referral to hospital.

The national ARI control programme in Pakistan recommends oral cotrimoxazole as the first-line antibiotic for the treatment of pneumonia because of its low cost, convenient twice-daily dosage schedule and wide availability. A community-based study reported a clinical treatment failure rate of 9% in children with non-severe pneumonia (NSP) treated with oral cotrimoxazole, but hospital-based studies had a higher failure rate of around 19%. Noorani et al. found that failure with cotrimoxazole therapy was significantly higher in those children who presented with wheezing on examination, which shows that the decision to prescribe antibiotic should be made after a trial of bronchodilator therapy.⁵³

The World Health Organization (WHO) recommends a 5-day course of co-trimoxazole (TMP/SMX) or amoxicillin for children <5 years of age with non-severe pneumonia living in less-developed countries. Pakistani investigators compared the WHO recommendation of 5 days to

3 days of antibiotic treatment in a double-blind, placebo controlled study conducted at 7 sites in 5 cities in Pakistan.⁵⁴ The proportion treated successfully was not statistically different between the 2 groups analyzed. A shorter course, if effective, would be more appropriate because it would decrease the overall antibiotic use in the treatment of pneumonias.⁵⁴

LHWs currently treat severe pneumonia with one dose of cotrimoxazole and refer to the nearest health facility for treatment. When referral is refused or not possible, no strategy exists to treat these children at home. Parents often seek care from local pharmacies or untrained providers, and in other instances receive nothing. A new study in Lancet followed 1,857 children who were treated at home with oral amoxicillin for five days and 1,354 children in a control group who were given standard care: one dose of oral cotrimoxazole and instructions to go to the nearest hospital or clinic.⁴⁵ The home-treated group had only a 9 percent treatment-failure rate, while the control group children failed to improve 18 percent of the time.⁴⁵ This study shows that lady health workers treating children with severe pneumonia in low socioeconomic areas can potentially work better than the established practice of advising parents to take them to a nearby hospital.⁴⁵

A randomized controlled multicenter trial was implemented in seven hospital outpatient departments and two community health programmes to compare the clinical efficacy of twicedaily cotrimoxazole in standard versus double dosage for treating non-severe pneumonia in children. The results showed that both were equally effective in treating non-severe pneumonia.⁵⁵ Another RCT showed that cotrimoxazole and amoxicillin had similar failure rates for treatment of non-severe pneumonia.⁵⁶

Barriers	Current efforts
 Demand side Expensive treatment of severe pneumonia for inpatients Lack of affordability and resources to seek care at health facility for severe pneumonia 	 MASCOT pneumonia study done by Pakistani investigators showed that 3 days of oral amoxicillin is equally effective as 5 days of amoxicillin for non-severe pneumonia.¹⁹ Hazir et al. recently showed that treating severe pneumonia at home with oral amoxicillin for 5 days can potentially work better.¹¹
Public sector	
 Pneumococcal vaccine not a part of EPI in the country as yet Failure of LHWs to recognize signs of pneumonia 	 ARI control program was launched in 1989 in Pakistan with emphasis on adopting WHO standardized guidelines of treatment, awareness on seeking medical care once respiratory symptoms appear in a young child. The pneumococcal vaccine will be available as part of EPI for free to all children in the country with support of GAVI by March 2012 LHWs are being trained in the recognition of pneumonia and prompt referral, but the program has, as yet, not focused on home management of severe pneumonia
Private sector	
 Over prescription of antibiotics in children with wheezing and underutilization of bronchodilator Failure of GPs and pediatricians to recognize fast breathing and chest in drawing as signs on pneumonia 	

Table 14: Current efforts for pneumonia

Malaria Specific Initiatives

History of malaria control in Pakistan dates back to the early sixties, when it started as the malaria eradication programme. After the resurgence of the disease during the early seventies, the programme strategy switched from "Eradication" to "Control". At the same time it was decided to integrate the programme into Primary Health Care in 1975. This strategic policy shift was in line with the WHO's call for "Health for All".

The National Malaria Control Programme was initiated in Pakistan in 1950. Later in 1961, Malaria Control Programme was revamped to Malaria Eradication Program, with the financial and technical support from WHO, United Nations Development Programme and The United States Agency for International Development. In 1977, Malaria control activities were integrated with the Communicable Disease Control Selection the Provinces.

Pakistan joined Roll Back Malaria partnership in 1999 initiated by the WHO in collaboration with the World Bank, Bill & Melinda Gates Foundation, UNDP and The United Nations Children's Fund. Since then it has been endeavoring to strengthen malaria control system in the country to achieve the Millennium Development Goal of near zero malaria induced deaths by 2015.

At present, Pakistan is a member of WHO Global Roll Back Malaria (RBM) Initiative, with a commitment to intensify its efforts for effective control of malaria in the country. Since its inception in 1948, WHO has been the major technical partner with the MOH in malaria control activities. Currently WHO provides technical and financial support to the RBM Programme for strengthening early diagnosis, prompt and effective treatment and epidemic control and operational research.

Objectives of the RBM Programme

- To reduce malaria morbidity by 50 % by end of the year 2010
- To reduce malaria mortality to minimum
- To prevent and control malaria outbreaks

The Directorate of Malaria Control was successful to win a grant of over US\$23 million in Round 7 of the Global Fund (GFATM).

Anti-malarial drug resistance has become a major challenge in providing an effective malaria treatment within many regions of the world. Recent P. falciparum resistance surveys indicated high failure rates (83%) in Chloroquine and Amodiaquine treated patients after 28 days of follow up y areas. WHO encourages the Combination therapy (Artemisnin-Based combination therapy ACT) as a major tool to control falciparum malaria. Based on these results national treatment policy has been revised to include the combination therapies with artemisinin derivatives (Artesunate + SP). which will be freely available at all malaria diagnosis and treatment centers in the target districts during the life of current proposal and will be sustained by the district, provincial and federal government after the completion of the project. Recently, Ministry of Health has taken a very bold step recently to put a ban on the production and use of monotherapies, consequently there is an urgent need for ACTs. As per national malaria policy, all confirmed falciparum malaria cases will be treated with ACT as first line drug. Some ACTs were received as a donation from some international agency during 2006 and were distributed among the high risk districts of the country. The results so far received are excellent against

complicated malaria cases. This shows the effectiveness of ACTs against complicated malaria in our scenario.

Table 15: Current efforts for malaria							
Barriers Current efforts							
 Public sector Continued high demand and sales of SP and mono therapies Lack of monitoring and evaluation in districts where "roll-back malaria" activities have been initiated. Inconsistent reporting on financing by the national government for malaria control efforts Inconsistent reporting on financing by the national government for malaria control efforts 	 During 2007, MoH imposed a ban on the use and production of oral artemisinin mono-therapies in Pakistan to ensure the rational use of anti-Malarial drugs and counter drug resistance. Existing outdated data recording and reporting tools have been reviewed and introduced in nineteen high-risk districts where Global Fund R-7 interventions are under implementation. The activity is being replicated in other parts of the country During 2009 the 1st ever Malariometric survey has been conducted in nineteen high endemic districts of the country through GFATM R-7 grant support Since the initiation of RBM Program in Pakistan in 2001 allocations from the public sector development program (PSDP) although have been increased from 239 million rupees to 658 million rupees for the years 2001-05 and 2008-2013 respectively 						
Lack of awareness regarding recent guidelines for malaria treatment among GPs and pediatricians	Guidelines and training manuals have been developed by directorate of malaria control, MOH on case management and vector control interventions in local languages						

PROPOSED INTERVENTIONS

This section proposes interventions and solutions that can help overcome the barriers to access of ORS, Zinc, amoxicillin and ACTS mentioned in the previous section. These barriers need to be addressed by combining efforts in both private and public sectors as well as increasing the demand.

Drug Management

Objectives:

- A central drug control body to cover all aspects of drug regulation
- Convene stakeholders to decide a framework and timeline for Implementation of drug policy
- Plan and conduct regular post marketing surveillance to assess the barriers at implementation level and keep a check and balance at the quality control
- Develop road map for introduction of newer vaccines like rotavirus

Rationale:

As mentioned in the earlier sections, the drug policy exists but is not implemented. After the devolution, powers have been transferred to the provinces and there is no clear roadmap, how it would be devolved. Many issues were cited regarding the regarding the regulation, procurement and supply of drugs. The current practice relied on incremental increase in inventory rather than a scientific forecasting based on morbidity data and patient volume statistics. Stock outs were a

commonly reported problem and felt to be more a problem of management of funds rather than non-availability of funds. Currently the drugs are procured from the cheapest tender submitted thus compromising with quality. Within the industry, the low threshold for drug registration was cited as a disincentive for manufacturers investing in quality. Those manufacturers with high quality products were driven by internal quality checks rather than regulatory pressures and relied on private market and exports for sales. Quality producers of drugs also tended to stay away from public sector procurement due to low priced tenders as well as concerns over government being a reliable payer. To overcome these issues, following activities are proposed

Activities:

- Central Body for Drug Control: A central body should be set up or the Drug Control Organization or NIH should have an epidemiological wing which would be responsible for forecasting and budgeting. It would carry out a survey and analyze the disease burden and scientifically analyze the requirements of essential drugs including ORS and zinc according to the districts of Pakistan. It should take into account the seasonal variations, demographics and the various age groups affected by diarrhea, malaria and pneumonia. Based on which forecasts should be made to improve the availability, distribution, procurement and sales for medicines (ORS, zinc, amoxicillin). This information would be shared with the district authorities who would ultimately be responsible for the procurement and supply of the drugs. This central body should keep a regular evaluation and monitoring system in place to ensure optimal supply of drugs round the year.
- Quality Control: Seven laboratories exist in Pakistan for Quality Control. Along with increase in laboratories, the strength of existing drug inspectors should also be increased and trained for efficient systems. The central body constituted would be responsible for approving brands for ORS, zinc and amoxicillin which meet all the quality standards. This will ensure consistency in the quality of the medicines by testing and approving brands for ORS, zinc, amoxicillin and ACTs. The district and provincial authorities would then be responsible for the purchase and storage of the medicines from only the approved brands. This measure will protect the public from hazards of substandard, counterfeit and unsafe drugs. This mechanism would also ensure consistent availability and quality of medicines.
- **Post Marketing Survey:** Independent post marketing surveillance on quality of medicine should be regularly conducted to keep a track of the issues and barriers for effective functionality.
- Introducing New Vaccines: Road maps should be developed for the introduction of Rota vaccine in the EPI program. Efforts should be made to improve the coverage rates for measles and HiB.
- **Monitoring and Evaluation:** Strict penalty should be implemented for violations of the law which make it possible for spurious drugs to gain access to the market such as fake licenses to sell, duplicate documents, absence of warranty of purchase of all products, gaps in the sale purchase record of all products, inadequate storage practices at outlets, and the absence of unqualified personnel at outlets. Hygiene and pest control should also be given a priority.

Partnering with Pharmaceutical Industry

Objectives:

- To develop a road map to reduce price gap between procurement and generic rates
- Develop collaborations with pharmaceuticals to identify existing demand and finding ways to meet them
- To ensure uniformity in quality among different producers.
- Develop plans to improve coverage and access to ORS and Zinc.

Rationale:

Initially NIH used to produce ORS but currently there is no public sector involvement in the production of drugs, therefore collaboration with pharmaceuticals is required to improve the quality, coverage and price of these medicines. There exists a wide gap in the procurement price of originator and generic brands. Also a knowledge-practice gap exists in the use of ORS amongst mothers. Mothers although being aware of the effectiveness of ORS for diarrhea, do not use it. One of the reasons for this gap is that mothers do not have easy access to ORS and zinc. To identify solutions to bottlenecks in the production and distribution of ORS and zinc and to increase the profitability of both products and encourage increased production, this collaboration is essential.

Activities:

- **Price regulation and rational selection:** The price gaps between procurement and generic brand rates need to be narrowed and could be done by partnering with pharmaceutical industry through price regulation and rational selection. Another cost cutting measure could be by providing incentives to suppliers in terms of reduced tariffs.
- Meet Demand: Pharmaceutical industries are not primarily interested in producing ORS due to its low cost. While Pakistan having enough capacity to meet zinc requirements, is not producing enough because pharmaceutical companies are unaware of the demand. Establishing partnership with pharmaceutical industry will help the industry to know the actual demand of ORS and zinc thus helping in creating a sustainable supply of ORS and Zinc. Information regarding the seasonal, demographic and age- group variability in the sales of the medicines would be shared with the pharmaceutical industry so they can have an understanding of the variations in the demand side for zinc, ORS and amoxicillin, so that these firms manufacture, distribute, and market their own brands accordingly. This increase demand will also invite competition which will help control price.
- **Improving coverage and access:** Through pharmaceutical industries, access can also be obtained to far flung and remote areas that otherwise do not have access to these commodities. Apart from improving coverage of these medicines, it would also help in controlling the price.
- Introduction of "Diarrhea Management Pack": The effectiveness of "Diarrhea Pack" (comprising low osmolarity ORS, Zinc, water purification tablets and pictorial instruction sheet in a single pack) has been tested in a trial and it was found that Diarrhea Pack is

acceptable in the community for the treatment of diarrhea. It has also been found that diarrhea pack can substantially reduce diarrhea burden and cost. The intervention has full potential to be scaled up at National level through the LHWs of National programme. By this collaboration, Diarrhea Packs can be introduced and promoted on a larger scale.

Warehouse and Logistics

Objectives:

- Develop appropriate storage facilities to preserve the drugs and ensure its availability
- Devise system to ensure the effective management and monitoring of medicine consumption in health facility
- Develop a system to enhance transparency in correct medicine use

Rationale:

Proper storage facilities don't exist at the national level and because of which drugs are destroyed and not adequately stored like following the floods in Pakistan in 2010, stocks of essentials medicines were destroyed.

Activities:

- **Building Warehouses:** Warehouses need to be built as drugs get destroyed and wasted due to lack of proper storage facilities. GDP certified warehouses and lists of these should be available with the public facilities. This would ensure continuous supply of medicines and reduce stock outs. Since medicines would be purchased and transported in bulk, warehouses would also help in reducing costs of transport of these medicines.
- Real-Time Inventory Management System: A Real-Time Inventory Management System (computerized drug management system) can be designed to ensure effective management and monitoring of medicine consumption in health facilities. In addition to providing comprehensive reports on medicine consumption patterns and regular updates on expired/out of stock medicines; this system will also allow key stake holders of the department to manage medicine requisitions and allocation to facilities. This system would ensure transparency in the supply of medicines. Storekeepers should also be trained on proper stock handling. EDL should be kept at all facilities. This system will also help keep a check on the correct use of medicines.
- **Electronic Bidding:** Drug procurement reforms centered on electronic bidding will have to be introduced and phased-in for enhancing transparency.

Scaling Up Community Programs

Objectives:

- To improve the existing knowledge base of LHW's
- To improve the functional capacity of LHW's
- Devise a plan to improve the referral facility

Rationale:

Currently, the burden on LHWs is high since one LHW covers around 1000 households. The refresher courses are also not that frequent.

Activities:

- Revision of LHW Curriculum: Revision of curriculum of LHWs, laying emphasis on the recognition of signs, appropriate management and counseling of care givers for diarrhea, pneumonia and malaria is required. Awareness amongst LHWs regarding the recent guidelines for the three diseases should also be increased and updated by refresher courses. Special emphasis should also be made to recognize the need to complete the duration of treatment. LHWs would be provided with pictoral algorithm cards which they can carry with them all the time to correctly diagnose and treat these diseases. The community part of IMCI should also be implemented.
- **Provision of appropriate diagnostic tools:** Providing them with up to date kits and appropriate diagnostic tools such as Rapid Diagnostic Tool for malaria and Breath Count Meter for pneumonia can help them in reaching to correct diagnosis and in giving referrals when required. There needs to be a strict evaluation and monitoring of the LHW system.
- Distribution of work: Reducing the burden on LHWs by either hiring more thus
 reducing load or dividing them for managing specific tasks for example, group of LHW
 should be responsible for providing immunizations, a separate group of LHWs for
 maternal health and family planning, and another group for providing disease
 management. This would help in ensuring that the lady health workers are focused
 towards their specific responsibility and are not over-burdened.
- **Incentives or Pay-on-performance:** Providing them with incentives such as pay per performance after regular check and evaluation to see if the area they cover has led to a reduction in one of the three diseases, can encourage them to perform more effectively.
- **Up gradation of Referral facilities:** These facilities need to improve in terms of equipment and supplies and also presence of specialists be ensured wherever possible.

Advocacy and Demand Generation

Objectives:

• Devise strategies to improve demand generation through mass media campaigns and other innovative means.

Rationale:

The demand for the treatment modalities lacks among the caregivers. Demand for ORS and zinc needs to be increased both at the consumer and prescriber levels. Education regarding the prompt recognition and consequently early treatment lacks. Awareness regarding the recognition of signs for pneumonia needs to be imparted among the GP's, LHW's as well as mothers.

Activities:

• Mass Media: Imparting health messages for improving care giver knowledge and treatment of the three childhood diseases through radio, short message service (SMS)

and cable TV channels so that care givers provide ORS together with zinc as the firstline treatment for uncomplicated diarrhea and are able to recognize danger signs in their child. Short daily messages in local languages could be beneficial.. With SIM registration now in Pakistan, targeted SMS can be sent. Radio is a cheap medium and also has wide rural coverage, so local figures can convey key messages through regular daily broadcasting.

- **Marketing Campaigns:** Distribution of posters, pamphlets and calendars carrying these messages in local language will be distributed among the masses. Road shows carrying these messages can also be displayed through projectors.
- Collaborating with producers of fast moving goods (FMGs): A survey should be conducted to identify the most widely used products (like tea sachets, milk, soap) and brands in specific areas and then by collaborating with the producers, public service messages regarding use of ORS and zinc can be imprinted on identified products. This will help in advocacy and organizations can also help fulfill their corporate social responsibility (CSR).
- **Community Education:** Education can be provided to care givers by LHWs through home visits and group activities at community level Collaborating with schools and Montessori can help in reaching mothers. Messages can be sent through the children in the form of written material to increase the awareness of mothers regarding zinc and ORS and change their perception regarding diarrhea treatment. Teachers can be involved by organizing "health days" in school imparting health messages on specific days. Mothers can be provided incentives in the form of basic necessities to encourage their attendance at such events

Educate private practitioners and chemists Objective:

• Devise strategies for continuous education of the practitioners and chemists

Rationale:

In Pakistan, mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses and paramedical staff More than 70% of care givers seek help from private sector with a major portion shared by General Practitioners. Unfortunately, knowledge of GPs regarding the recognition of important signs for pneumonia and appropriate management for pneumonia, diarrhea and malaria is lacking. The mean number of drugs per prescription is higher for general practitioners than public providers. Prescription rate is particularly higher for antibiotics and injections amongst GPs as compared to public sector. Similarly more GP prescriptions had an intravenous infusion compared with public providers. General practitioners also prescribe anti-diarrheals more frequently than doctors working in the public sector.. Care givers also often refer directly to chemists for purchasing drugs for diarrhea, pneumonia and malaria, so they also need to be educated and medicines retail associations involved in this process.

Activities:

- Continued Medical Education (CME) seminars and workshops: Organizing Continued Medical Education (CME) seminars and workshops emphasizing on these three illness and the guidelines for their management can help in influencing GPs in providing appropriate management. GPs who participate in CME seminars would be provided with accreditation.
- Training Chemists: Providing some level of training to chemists regarding management of these diseases would prove beneficial. Education materials in the form of brochures, posters and hand bills providing information in local language advocating the usage of ORS and zinc for diarrhea and usage of zinc for the complete duration can be placed at point-of-sales. Apart from regulating quality of drugs, regulation of drug retail outlet be ensured.

Financial schemes

Objectives:

• Devise a plan for implementing various financial schemes to scale up treatment uptake by caregivers..

Rationale:

63% of the total drug expenditure is borne by households, one of the highest in developing countries, as opposed to only 18% in OECD countries and leads to non-compliance with chronic care treatment and risk of catastrophic expenditure. The public sector in Pakistan spends merely \$5 per capita when compared with other countries with similar income levels. Spending by public sector is only 34% of total health expenditure and of that less than 25% is spent on non-salary items including medicines. Patients incur costs for medicines at both public and private sector facilities with drug shortages in public sector forcing patients to private retail pharmacies. Patient spending on medicines at public sector facilities is considerable at Rs198 on medicines / visit versus Rs258 per visit at private sector facilities. At present there are no pre paid schemes and commodity vouchers to ensure patient compliance with therapy and protect households against catastrophic expenditure.

Activities:

• **Conditional Cash transfers or Voucher Schemes** can be introduced for rapid uptake of desired treatments. This would also ensure compliance. Possible mechanisms include franchising with GPs, contracting with NGOs, commodity vouchers, health equity funds and pre-payment schemes, to supplement public sector provision.

PROPOSED INTERVENTIONS TIMELINE

		ESSENTIAL MEDICINE INITIATIVE														
		2012 2012						POSEDINI							46	
		2012			01	2013			2014				2015			
Intervention 1	Drug Management	ų∠	ųs	Q4	ŲI	Q2	ųs	Q4	ų	ųΖ	ζy	Q4	QI	ųz	цэ	Q4
Activity 1.1	Central Body for Drug Control															
Activity 1.1.1	Epideiological Survey and Forecasting															
Activity 1.2	Quality Control															
Activity 1.2.1	Hiring and Training of Drug Inspectors															
Activity 1.2.2	Approving brands															
Activity 1.3	Post Marketing Survey															
Activity 1.4	Introducing New Vaccines															
Activity 1.4.1	Rotavirus Vaccine															
Activity 1.4.2	Pneumococcal															
Activity 1.4.3	Increase Coverage of Hib and Measles															
Activity 1.5	Monitoring and Evaluation															
Intervention 2	Partnering with Pharmaceutical Industry															
Activity 2.1	Price regulation and rational selection															
Activity 2.2	MeetDemand															
Activity 2.3	Improving coverage and access															
Activity 2.4	Introduction of "Diarrhea Management Pack"															
Intervention 3	Warehouse and Logistics															
Activity 3.1	Building Warehouses															
Activity 3.2	Real-Time Inventory Management System															
Activity 3.3	Electronic Bidding															

PROPOSED INTERVENTIONS TIMELINE (Contd)

Intervention 4	Scaling Up Community Programs]							
Activity 4.1	Revision of LHW Curriculum								
Activity 4.2	Provision of appropriate diagnostic tools								
Activity 4.2.1	Rapid Diagnostic Tool								
Activity 4.2.2	Breath Count Meter								
Activity 4.3	Distribution of work								
Activity 4.4	Incentives or Pay-on-performance								
Activity 4.5	Up gradation of Referral facilities								
Intervention 5	Advocacy and Demand Generation								
Activity 5.1	Mass Media								
Activity 5.1.1	SMS								
Activity 5.1.2	Radio								
Activity 5.1.3	Cable TV								
Activity 5.2	Marketing Campaigns								
Activity 5.2.1	Posters, Pamphlets and Calendars								
Activity 5.2.2	Projector Road show s								
Activity 5.3	Collaborating with producers of FMGs								
Activity 5.4	Community Education								
Activity 5.4.1	School Health Days								
Activity 5.4.2	Community Group Activities								
Intervention 6	Educate GPs and chemists								
Activity 6.1	CME seminars and workshops								
Activity 6.2	Training Chemists								
Activity 6.2.1	Training								
Activity 6.2.2	Promotion Materials								
Activity 6.3	Regular monitoring								
Intervention 7	Financial Schemes								
Activity 7.1	CCTs or Voucher Schemes								

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