ANNEX 1. PAKISTAN STUDY PROTOCOL

[REDACTED VERSION]

FULL PROTOCOL EMBARGOED, PENDING PEER-REVIEWED PUBLICATION

SUMMARY

This study will be implemented under the DFID-funded consortium on Research on Food Assistance for Nutrition Impact (REFANI), of which ENN and Action Against Hunger are partners. Between March 2014 and February 2017 the consortium members will undertake up to three studies where an NGO is implementing a Cash Transfer Programme (CTP) involving cash or voucher transfers, in response to humanitarian need. The focus of the studies is to examine the effect of CTP on the nutritional status of young children.

Country: Pakistan

Title: A cluster randomised controlled trial to measure the effectiveness and costeffectiveness of different cash transfer programmes at reducing the risk of undernutrition in 6-59 month old children and mothers.

Aims: This study aims to test the effectiveness and cost effectiveness of different Cash Transfer Programmes (CTPs) on reducing the risk of undernutrition in children 6-59 months and their mothers in Dadu District, Sindh Province, Pakistan. Specifically, our primary objectives are to compare whether using seasonal unconditional CTs or voucher transfers has a greater impact on the reduction of wasting in children 6-59 months compared to a comparison group that receives the standard Women and Children/Infant Improved Nutrition in Sindh (WINS) intervention only.

Design: The design is a pragmatic longitudinal cluster randomised controlled trial (cRCT) with 3 parallel arms that will compare 2/3 cash transfer (CT) interventions (cash, food voucher (and double cash)) to a comparison area. All arms (including the comparison area) will have access to Action Against Hunger | ACF International (ACF) WINS programme (an integrated FSL, WASH and nutrition education intervention). Allocation of the arms to either the intervention or comparison areas will be done randomly. Our primary outcome is prevalence of acute malnutrition (as measured by weight-for-height Z-score <-2 or the presence of pitting oedema) in children 6-59 months of age. Impact will be assessed at 6 months and 1 year after baseline. The Pakistan REFANI study will employ a mixed-methods approach using both quantitative and qualitative methods to determine the impact (the what) and the processes involvedⁱ (the how), as well as the costs involved from a cost effectiveness analysis (CEA). Recognition is growing that there is a need to understand this complexity if future intervention development is to be informed, or efforts to apply the same intervention in another setting or population are to be made.

Acknowledgements: This protocol was developed with support from REFANI consortium members, DFID (UK Aid), Nutrition Research Steering Committee members and ACF International, especially Aamir Mohammad (FSL Coordinator Pakistan) and Shahid Fazal (Nutrition Coordinator Pakistan). We would particularly like to thank them for their valuable contributions, the ACF teams in Pakistan, especially Erin Hutchinson (CD), Shazad Ajmal Paracha (Programme Quality and Accountability Coordinator), Brian Hansen (Field Coordinator in Dadu); in New York, Maureen Gallagher (Senior Nutrition and Health Advisor), Dr. Mulugeta Handino (FSL advisor), Jaimie Shaff (Field Finance Officer), Silke Pietzsch (Technical Director). As well, we would like to thank Dr. Andre Briend (Prof Emeritus Helsinki University) for his valuable inputs.

ⁱ These processes may either hinder or promote good nutritional status through CTPs.

ABBREVIATIONS

ACF	Action Against Hunger ACF International
BISP	Benazir Income Support Programme
ССТ	Conditional Cash Transfer
CEA	Cost Effective Analysis
CFV	Complementary Food Voucher
CI	Confidence Interval
СМАМ	Community-based Management of Acute Malnutrition
CONSORT	Consolidated Standards of Reporting Trials
cRCT	Cluster randomised control trial
СТ	Cash Transfer
СТР	Cash Transfer Programme
CW	Concern Worldwide
DEWS	Disease Early Warning System
DoH	Department of Health
ENN	Emergency Nutrition Network
EU	European Union
FATA	Federally Administered Tribal Areas
FDG	Focus Group Discussions
FV	Food Voucher
GAM	Global Acute Malnutrition
GDP	Gross Domestic Product
GII	Gender Inequality Index
GNI	Gross National Income
GoP	Government of Pakistan
HAZ	Height (length)-for-Age z-score
HEA	Household Economy Approach
HFIAS	Household Food Insecurity Access Score
HSS	Health Sector Strategy
ICN	Individual Case Narratives
IDI	In-depth Interviews
IDP	Internally Displaced Population
ISRCTN	International Standard Randomised Controlled Trial Number
IYCF	Infant and Young Child Feeding
IPC	Integrated Food Security Phase Classification
КАР	Knowledge Attitudes and Practices
KI	Key informant interviews
КРК	Khyber Pakhtunkhwa
LHW	Lady Health Workers
MAM	Moderate Acute Malnutrition
MPI	Multi-Dimensional Poverty Index
MUAC	Mid-Upper Arm Circumference
NCA	Nutrition Causal Analysis
NCHS	National Centre for Health Statistics
NDMA	
	National Disaster Management Authority
NIS	Nutrition Surveillance System
NNS	National Nutrition Survey
ODF	Open Defecation Free
OTP	Outpatient Therapeutic Programme
PDMA	Provincial Disaster Management Authority
PINS	Pakistan Integrated Nutrition Strategy
SAM	Severe Acute Malnutrition
SC	Save the Children International
SFP	Supplementary Feeding Programme

SQUEAC	Semi Quantitative Evaluation of Access and Coverage
SSN	Social Safety Net
TFP	Therapeutic Feeding Programme
UC	Union Council
UCT	Unconditional Cash Transfer
WAZ	Weight-for-age z-score
WHZ	Weight-for-Height z-score
WHO	World Health Organisation

1. BACKGROUND RATIONALE

1.1 Pakistan

Geography and Economy

Pakistan is a federal parliamentary republic consisting of four provinces (Figure 1): Punjab, Sindh, Khyber Pakhtunkhwa and Balochistan, and four federal territories: the Islamabad Capital Territory, two disputed territories and the federally administered Tribal Areas in the northwest (including the Frontier regions). Below this, there are four more tiers of government, including 27 divisions, over a hundred districts (zillahs), more than four hundred sub-districts (tehsils), and several thousand union councils (UCsⁱⁱ).

Figure 1: Map of Pakistan with provinces



Pakistan is divided into three major geographic areas: the northern highlands, the Indus River plain and the Balochistan Plateau, and has a diverse range of landscapes among nine major ecological zones. Pakistan's economy is largely agrarian, contributing about 24% of the Gross Domestic Product (GDP). Most of the population live in rural areas (64%)¹ and 45% of the population, made up mostly of womenⁱⁱⁱ are actively involved either directly or indirectly in the agricultural sector.^{2,3,4,5}

Climate Variability in Pakistan

The climate varies from tropical to temperate, with arid conditions in the coastal south. There are four distinct seasons: a cool, dry winter (December – February); a hot, dry spring (March – May); a summer rainy season (June - September); and a retreating monsoon (October - November). Rainfall varies greatly from year to year, and patterns of alternate flooding and drought are common.

Pakistan is prone to disaster, most notably flooding (especially in 2010, 2011-2013), but also earthquakes, cyclones and droughts, and is among the World's Top 10 countries in terms of vulnerability to the impacts of climate change.⁶ The cost of adaptation to this threat is estimated at \$10.7 billion per year for the next 40-50 years^{iv}.

The risk that flooding will be considered a disaster depends on three factors: "the hazard associated with the flood; the exposure of human and natural systems to the floodwaters; and the vulnerability of these systems to

ⁱⁱ A union council (UC) or *sherwan* is an elected local government body headed by a *nazim* (which is equivalent to a mayor) and a *naib nazim* (deputy). Union councils are the fifth tier of government in Pakistan which is part of a *tehsil/taluka* (a district subdivision) or, less commonly, part of a city district.

[&]quot;e.g. 70% of women in Sindh,

^{iv} From Pakistan One UN Programme 2013-2017 www.unicef.org/.../PAK_One_UN_Programme_II_(2013_-2017)_Doc.

flooding".^{7,8} The frequency and intensity of extreme flooding is likely to increase with climate change,⁹ along with the number of people at risk of being exposed to flooding.¹⁰

Increasing population size has led to inappropriate settlements being built on drained flood plains exposing large numbers of people to increased risk of flooding during monsoon periods. Whilst efforts have been made to reduce small localised flooding and protect the land for settlements and cultivation, there has been a trade-off resulting in a river system with little flexibility and ability to absorb heavy rainfalls which climate scientists predict will occur with increasing frequency.¹¹ The National Disaster Management Authority (NDMA) was set up in 2005 after the earthquake in Kashmir to prepare for future natural disasters and flooding^v. However, there has been a gap between policy and practice, blamed on a lack of resources and capacity at provincial and district levels, resulting in a lack of investment in disaster risk reduction.⁶

Conflict in Pakistan

Since independence (1947), there have been three wars against India, several border skirmishes with Afghanistan, and an extended border skirmish with India in 1999 and military operations against armed groups along the border areas of Afghanistan. There are currently four areas of conflict within Pakistan: Sectarian violence (mainly between Sunni and Shi'ite Muslims, but more recently in Karachi^{vi}, home of the Quetta Shura Taliban, with the recent attack on the airport in June 2014); Baluchistan; North and South Waziristan; and the Swat Valley. Aside from this, there are localised killings of teachers and health workers (e.g. polio vaccination staff) as these are seen as delivering anti-Muslim propaganda.

Development Indicators

Pakistan is the sixth most populated country in the world (approx. 185,000,000; 36.7% of which are younger than 14 years¹²) with a population expected to double by 2045.¹³ Nearly half (49.4%) of the population is considered to be in Multi-Dimensional Poverty^{vii} and the country is ranked 146 out of 186 countries on the Human Development Index (HDI) [or (98/132) on the Inequality adjusted Human Development Index (IHDI)].¹ Pakistan is classified as a 'low human development' nation¹ and has shown no improvement in human development indicators over the past 10 years in what has been described as the 'lost decade',⁴ despite an improvement in economic growth and reduction in poverty headcounts during this period.

About 21%^{viii} of the population live below the international poverty line of US\$1.25 a day (down from 22.6% in 2005) with approximately 60% living on less than \$2 a day (2008)⁴. Gross National Income per capita (GNI PPP) is \$4,670 (2014), which ranks Pakistan 156th out of the 213 countries.⁵

Life expectancy at birth was 66 years for females and 64 years for males in 2012⁵. Globally, Pakistan ranks third for the highest burden of maternal, foetal and child mortality.¹⁴ Mortality of the under five years of age was 86 per 1,000 live births in 2012. Data from 1990 to 2010 shows that in the 90s, Pakistan, India, and Myanmar had the same rate of under five years of age-mortality, and Bangladesh and Nepal were worst off. However, all of these countries improved their rates by 2000 and by 2010; they had drastically lowered their under-5 mortality ratios and are now on track to achieve their millennium development goals (MDGs). Pakistan is however unlikely to achieve these, or mother and child MDG nutrition targets.¹⁵

Pakistan is ranked 57 out of 79 countries (equal with Lao PDR and Rwanda) on the Global Hunger Index (GHI)^{ix} with a score of 19.3 in 2013^x (down from 25.5 in 1990).

In 2012, the total expenditure on health per capita was \$91 representing 3.2% of GDP (whilst up from 2.6% in 2009, the increase was not higher than the mean increase globally)¹⁶. The health care system in Pakistan is a

^{vi} Previously declared a war zone by Amnesty International.

 $^{^{\}rm v}$ Considered outside the 'natural' disaster realm since flooding can be avoided.

^{vii} Poverty can be measured more comprehensively using the MPI, which looks at overlapping deprivations in health (nutrition & mortality), education and standard of living. The MPI is the product of the multidimensional poverty headcount (the share of people who are multi-dimensionally poor) and the average number of deprivations that each multi-dimensionally poor household experiences (the intensity of their poverty).

^{ix} The GHI incorporates three interlinked hunger-related indicators: proportion of population undernourished, prevalence of underweight children, and the child mortality rate.

^x http://www.ifpri.org/ghi/2013

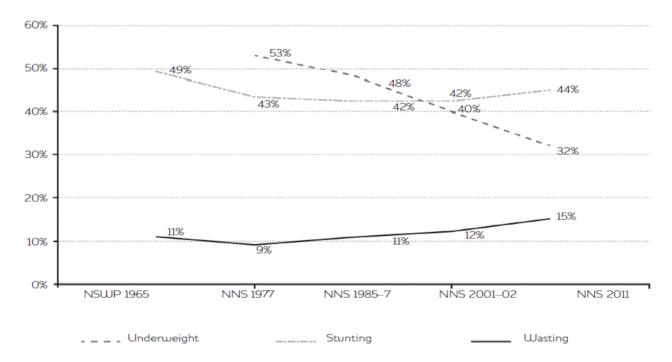
mixture of private and public with about 80% of the population accessing health care through private consultations. The public system is poorly financed while within the private sector, there is lack of regulation on top of governance limitations that have led to access, quality, and equity issues¹⁷.

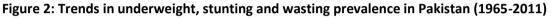
Since the devolution of the Ministry of Health from federal to provincial level in April 2010, whereby provinces and regions have been given greater responsibility for nutrition and health, and the more recent floods, there has been a greater focus on both wasting and stunting culminating in the remarkable findings from the recent National Nutrition Survey (NNS 2011)¹⁸ evidencing a worsening of nutritional status in Pakistan. These factors combined to create greater momentum for nutrition.¹⁹

The burden of Mortality and Undernutrition

One in every five children in the developing world is malnourished, and undernutrition is associated with nearly half of all child deaths globally. ^{20,21} It has been estimated in Pakistan that 35% of child deaths are linked to undernutrition.¹⁸

Undernutrition in Pakistan is a persistent problem that is province-wide, and found in urban and rural areas across a range of income groups. Improvements in macro level economic growth and an increase in food availability have not translated into improved nutritional status. As shown in Figure 2 and Box 1 below, over the past decade, child stunting and wasting has increased to 44% and 15% respectively.





Source: NNS 2011 - taken from Bhutta et al. 2013a

Due to its high population growth, the actual number of children who are stunted in Pakistan has doubled since 1985⁴. Pakistan remains in the top 30 countries (out of 136) with highest rates of stunting²² while the national prevalence of wasting is classified as 'critical'²³, with an estimated 1.5 million children being acutely malnourished.

National data showed that 18% of women were underweight (BMI < 18.5 kg/m^2 ; 14.4% in urban areas; 19.7% in rural areas). However, 19.3% of women of reproductive age were overweight and 9.5% obese (although the difference is notable for urban (15.7%) compared to rural areas (6.5%)].¹⁸

Declines have also been notable for micronutrient status among children and mothers, especially for Vitamin A and anaemia status (62% of non-pregnant women in Sindh are anaemic¹⁸). The only micronutrient deficiency disease to show improvement in both mothers and children was iodine (due in part to Government commitments and donor support and sustained efforts to reduce iodine deficiency). Levels of Zinc deficiency remain unchanged. The long term effects of undernutrition in Pakistan are estimated to cost 3% of the GDP

annually; losses of nearly USD3 billion in GDP are due to micronutrient deficiencies; childhood anaemia alone is associated with a 2.5% drop in adult wages.²⁴

	NNS	NNS
	2001	2011
Children under 5 years		
Stunting	42	44
Wasting	14	15
Underweight	32	32
Anaemia	51	63
Vitamin A deficiency	13	54
Zinc deficiency	37	39
Children between 6 - 12 years		
lodine deficiency	42	12
Women (Non-pregnant)		
Underweight (BMI < 18.5)	NA	14
lodine deficiency	58	14
Anaemia	29	50
Vitamin A deficiency	6	42
Zinc deficiency	42	42

1.2 Undernutrition

The immediate causes of undernutrition are a poor diet and disease. A child can be wasted (low weight-forheight^{xi}; <-2SD) or stunted (low height-for-age <-2SD), or both wasted and stunted. Both wasting and stunting are associated with high mortality particularly if a child is both wasted and stunted; and in severe forms (<-3SD). Wasting and stunting are physiologically linked²⁵ and share common causal pathways so interventions to address one condition could be beneficial to the other condition.

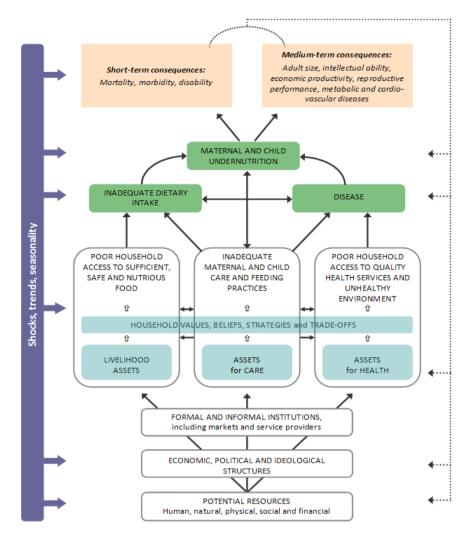
In terms of risk for mortality then, both severe stunting (<-3 SD) and mid upper-arm circumference (MUAC) <115 mm are better at identifying those at higher risk of mortality than weight-for-height. Children with severe stunting carry a significantly higher risk of death than those who are moderately wasted (5.5 (4.6-6.5) compared to 3.4 (2.9-4.0)). However, for children who are both wasted and stunted the risk of death is higher, 12.3 (7.7-19.6).²⁵

Micronutrient deficiencies (MND) have been described as a hidden form of undernutrition, but are major threats to health and development particularly of pre-school children and PLW in low-income countries. Micronutrients are needed in small amounts and are essential for growth and development. Consequences of their absence are severe. The most important public health concerns include Vitamin A, iron and iodine deficiencies.

However, for all children under five years, undernutrition also increases susceptibility to and incidence of infections and is associated with a diminished response to vaccines.²⁶ The starting place for undernutrition in childhood is complex with a variety of direct and underlying contributors related to lack of food, including insufficient breastfeeding and inadequate complementary foods (Figure 3); protein and nutrient loss from multiple respiratory and gastrointestinal infections; chronic immune stimulation due to persistent parasitic intestinal infections; and, inadequate water and sanitation.^{27,28}

^{xi} In comparison with a well-nourished reference population (WHO 2006).

Figure 3: ACF adopted Nutrition Framework based on the UNICEF model



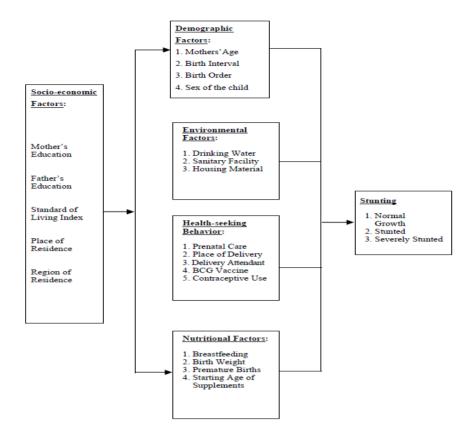
2. STUDY CONTEXT 2.1 Causes of undernutrition in Pakistan

Infrastructure/Capacity

Whilst the Government of Pakistan (GOP) is aware of the problem of undernutrition, there have been few interventions to tackle it.⁴ A report by the World Bank suggests that the lack of progress in undernutrition has been due to a number of limiting factors such as low investment in nutrition activities, lack of clarity on the roles of the different parts of GOP, lack of political commitment to systematically address undernutrition, lack of human resources for fulltime engagement on nutrition activities, lack of strong and sustained leadership, and inaccurate and inadequate information on nutrition status, behaviours, and coverage of services²⁹. This last point has been highlighted by others.^{30,31} As a result the available evidence for the causes of undernutrition in Pakistan is also contradictory.

Income/Economic Growth

It is expected that the determinants of undernutrition will vary across geographical region and urban and rural areas.³² However, as the recent NNS showed, undernutrition is a problem that affects many income groups and not just the poorest.¹⁸ Household income growth alone may not be sufficient to reduce undernutrition, especially in the short term and that other factors need to be examined, e.g. availability/accessibility of services (e.g. infrastructure, nutrition information, health services), local norms and culturally-driven behaviours.¹⁷ Using data from the 1990-91 Pakistan Demographic and Health Survey (PDHS), Mahmood developed an early model showing the importance of income, household sanitation as well as the education level of both parents as significant determinants of stunting (Figure 4).³²



That improvements in nutritional status in Pakistan have not coincided with economic improvements is unsurprising. A study carried out by Vollmer³³ on 121 Demographic and Health Survey (DHS) countries saw no association between increases in per-head GDP and reductions in early childhood undernutrition (stunting, wasting or underweight). The reasons for this have been suggested to be: unequal distribution of economic growth within countries leaving poorer households unaffected; increasing national incomes do not guarantee the public investments necessary to reduce child undernutrition (e.g. clean water and sanitation or vaccination against diseases related to undernutrition); and households may not spend increasing incomes in ways that improve nutrition. In order to tackle undernutrition in children in low-income and middle-income countries, direct investment in health and nutrition interventions are necessary.³³ However, others argue that economic growth, whilst potentially having a limited impact on undernutrition, is useful, especially for longer-term outcomes³⁴. Haddad et al. agree that investments in direct interventions are necessary³⁴ and this has been recognised in some countries (e.g. Vietnam³⁵).

Poverty/Food Insecurity^{xii}

Poverty and food insecurity have been identified as key risk factors for child undernutrition. Yet neither has been thoroughly investigated as determinants of undernutrition in Pakistan. A recent study by Arif et al³¹ using the 2010 'Pakistan Panel Household Survey' (PPHS) showed no association between poverty and child nutritional status in Pakistan but did show that disease (especially diarrhoeaxiii), nutritional status of children's own mothers and other environmental (e.g. WASH) and community factors (such as health care services – especially those provided by Lady Health Workers (LHW)) were more important determinants of nutrition status than poverty.

Iram et al. suggest that Pakistan is not a food insecure country as it "generally has the economic ability to import food".³⁶ However, food insecurity (especially in terms of economic access by the poorest to an adequate and diverse diet) does exist in certain geographic regions and especially so during times of stress (which are often). The cost of the food basket has risen by 80% between 2007 and 2011³⁷, and Pakistani households now

^{xii} Food security comprises three main components: availability, access and utilization. Sen AK. Poverty and famines: An essay on entitlement and deprivation. Clarendon Press; 1981.

⁻ Availability is often measured through proxies at the population level, such as national agricultural output, while access and utilization are more often measured at the household and individual levels respectively. Barrett CB. Measuring food insecurity. Science 2010 Feb 12;327(5967):825-828.

xiii The direction of causality was not assessed here – the presence of diarrhoea could have been a cause of undernutrition.

spend on average 48.9% of their income on food whilst the lowest two quintiles spend 57-60% of their income on food.³⁸

In rural areas, it has been estimated that 67% of districts are food insecure [in terms of access (mainly economic) to food] and among these 46% are severely food insecure.³⁹ In urban areas, food insecurity has been identified as a major contributing factor to increasing undernutrition in young children in urban squatter settings.⁴⁰ The study by Iram et al. concluded that "food security measures alone may have a limited effect on the nutritional well-being of individuals, unless the reinforcing detrimental linkages between [household] food insecurity, disease, poor sanitation and inadequate education are addressed".³⁶ These factors are exacerbated by lack of public policy action and persistent economic inequalities.

However, the evidence around income, poverty and undernutrition in Pakistan can be confusing and somewhat contradictory especially when trying to explain why Pakistan, despite economic growth, has shown no improvements in undernutrition. Bhutto et al. report, "the relationships [in the causal framework] are complex and influenced by female subjugation and it is difficult to fully unpack the evidence around this."¹⁴

The emerging evidence from both quantitative and qualitative studies carried out in Pakistan on the causes of undernutrition also agree with the importance of household income as well as other drivers of nutritional status like intra-household food allocation (favouring males), mother's education and knowledge (especially around child care), health (knowledge and treatment, especially diarrhoea), sanitation, women's health and nutrition status and women's lack of empowerment and involvement in decision making.^{3,4,18,30,31,32,41,42}

Gender Inequalities

Pakistan is a patriarchal society with large disparities (in empowerment, health and labour) between men and women. Pakistan ranks 123rd out of 148 countries on the Gender Inequality Index (GII^{xiv})⁴³ which is a new composite indictor to measure inequalities between men and women. Women's empowerment^{xv} is an important factor in improving children's (and their own) nutritional status.^{44,45,46,47} The study by Smith et al. estimated that in South Asia, if women and men had equal status then the rate of underweight in children less than 3 would drop by 13 percentage points.⁴⁷

The 'feminisation' of poverty in South Asia has ultimately resulted in a lack of investment in women's health and poor access to services.⁴⁷ Underpinned by gender inequality there is limited recognition of the rights of poor women to good maternal health services. In South Asia the pathways identified through which empowerment has an effect on child nutritional status are women's own nutritional status (as measured by body mass index [BMI]), prenatal and birthing care for women, complementary feeding practices for children, treatment of illness and immunisation of children, and the quality of substitute child caretakers.⁴⁷ These go hand-in-hand with important proximate determinants of mother and child undernutrition identified in Pakistan (i.e. low literacy rates among women, early marriages, high fertility rates with lack of birth spacing, and poor access to health care facilities).⁴

Infant and Young Child Feeding

Pakistan has poor indicators for infant and young child feeding (IYCF), especially around breastfeeding practices and lack of knowledge on food choices which have resulted in the use of complementary foods that are micronutrient and have poor bioavailability.⁴ Although approximately 90% of women breastfeed their children, only half (50.5%) of women started breastfeeding within one hour of birth, the remaining discarding colostrum considering it as a waste product or impure milk unsuitable for their newborn babies. Just 16% of mothers exclusively breastfeed their children in the first four months.¹⁸ The NNS 2011 also concluded that the introduction of inappropriate complementary foods and unsuitable food choices are common, and that these are likely to result in increased risk of diarrhoea and undernutrition.¹⁸

At the time of the NNS, 12% of children nationally were suffering from diarrhoea and approximately a quarter of children (22.3%) had diarrhoea during the two weeks prior to the NNS household visit (Figure 5). Rates for diarrhoea (current and during the past 2 weeks) are similar in most areas except Khyber Pakhtunkhwa (KPK), Federally Administered Tribal areas (FATA) and Balochistan where rates were significantly lower.

xiv According to the UNDP, this index is a composite measure which captures the loss of achievement, within a country, due to <u>gender inequality</u>, and uses three dimensions to do so: <u>reproductive health</u>, <u>empowerment</u>, and <u>labour market</u> participation.

^{xv} Defined in terms of control of resources and autonomy, workload and time and social support networks.

Water and Sanitation

A potable source of water and appropriate hygiene practices are important to reduce diarrhoea (and water borne infectious diseases) thereby reducing the risk of undernutrition.⁴⁸ Rates of treatment of water are very low in rural households: only 8% of households reported treating water. Even in urban areas, rates of water treatment were low, with only 31% of households treating water.¹⁸

Hand washing practices in both urban and rural Pakistan are reported to be generally very good both after defecation (>98%) and before meal preparation (>95%). However, the use of soap in hand washing was much less common; 50% in rural areas and 75% in urban areas. Of greater importance is open defecation; a third of households in rural areas do not have a toilet facility^{xvi} and there is currently a push for WASH interventions and Open Defecation Free (ODF) interventions. However, it may be that reporting on the number of ODF areas has been subject to upward bias (personal communication DFID; June 2014).

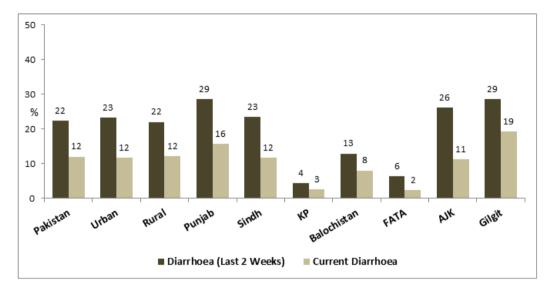


Figure 5: Prevalence of Diarrhoea (NNS 2011)

2.2 Undernutrition in Sindh

Sindh (Figure 6), located in the east of the country, is the 3rd largest province of Pakistan (2nd largest in terms of population) and is divided into 23 districts, 113 tehsils (talukas^{xvii}) and 1,703 UCs with a current estimated population of 43 million in 2011.

Figure 6: Map of Sindh province



^{xvi} Water and sanitation Programme http://www.wsp.org/ ^{xvii} Tehsils are called Talukas in Sindh.

There are 18 District hospitals, 44 taluka hospitals and 125 rural health centres in Sindh. The population is roughly equally split between urban (47%) and rural (53%) areas and between men (53%) and women (47%) (Sindh Health Sector Strategy (HSS)). Sindh has the highest population growth rate in the country at 3.2%. Fifteen percent (17% rural and 13% urban) of the population is under five years of age (Sindh HSS).

To the east of Sindh is the arid Thar Desert, to the west the Kirthar Mountains and the Arabian Sea to the south. The Indus River (from which the name Sindh originates) provides expansive, irrigated plains in the centre. The climate is tropical to sub-tropical with an average rainfall of around 18cm. The position of Sindh means that it is not affected by either of the two monsoons directly although the low rainfall is supplemented by the Indus River twice a year which swells from rainfall during the monsoons and melting Himalayan snow.

Recurrent natural disasters in Sindh

Sindh is a disaster-prone area, with recurrent natural disasters such as floods, cyclones, drought, extreme high temperatures and earthquakes. The main problems occur with flooding.

Sindh has two different sources of floods; those related to the Indus River inflow and those related to heavy rains. The Indus River has been responsible for 11 major floods in Pakistan prior to 2010 (including most notably those in 1950, 1955, 1956, 1973, 1976, 1988, 1992, 1997 and 2005). In 2010, 2011 and 2012, Sindh experienced extensive floods (both flash and monsoon floods) which resulted in substantive damage to crops, services and infrastructures, consequently slowing down developmental and economic activity. These floods prompted the Provincial Disaster Management Authority (PDMA) to plan a multi-hazard contingency plan for the 2013 monsoon season providing food and non-food assistance for 1million households over 3 months.⁴⁹ In 2013, 4000 people were displaced in Dadu due to flooding. In comparison, the 2010 and 2011 floods affected roughly 7.2 million (including 1.8 million internally displaced people^{xviii}) and 9.2 million people in the province with the most damage to sectors of agriculture, housing and infrastructure.⁴⁹ Figure 7 shows the flood affected areas (and severity) in 2010.

The 2010 floods in Pakistan caused 1985 deaths and injured 2946 people. Twenty percent of these deaths and 41% of injuries occurred in Sindh Province.⁵⁰ The immediate results were food insecurity and outbreaks of disease^{xix},⁵¹ in affected districts putting strain on health facilities, of which 11.7% were destroyed and many of the LHWs displaced, increasing vulnerability to undernutrition.

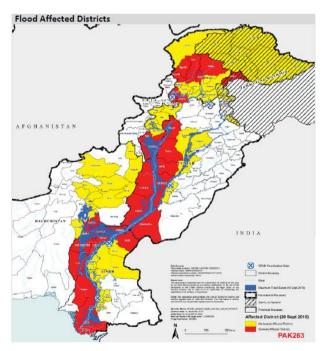


Figure 7: Flood affected areas in Pakistan (red is severely affected)

^{xviii} The floods occurred in July/August 2010 – by the end of Dec 2010 almost 75% of IDPs had returned to places of origin. ^{xix} Report from the Disease Early Warning System (DEWS) that the most common illnesses included: acute respiratory infection (23%), skin diseases (11%), acute diarrhoea (9%) and suspected malaria (6%).

The World Food Programme Flood Impact Assessment reported that at least 10.1 million people were in need of emergency food assistance, with an estimated 3.6 million people needing long-term assistance. Risks of diarrhoeal outbreaks caused by water borne diseases from contaminated water, poor IYCF, food insecurity and loss of livelihoods increased the susceptibility of a displaced and affected population to stunting and wasting.^{52,53} The floods exacerbated pre-flood acute malnutrition rates causing these to rise from 13.2% to between 22.6% in the North of Sindh to 26% in the South of Sindh.⁵⁰

Pakistan suffered a prolonged drought from 1999 to 2002.⁵⁴ This year (2014) certain parts of Sindh have been affected by lack of rainwater and the GoP has declared a state of emergency in 4 UCs of Umerkot and Tharparkar. These UCs are south east of Dadu. However the more arid areas of Dadu (Kachho - vast areas of flat land) where livelihoods are dependent on rain, remain vulnerable to the risk of drought.⁵⁴

Undernutrition in Sindh

Sindh has the highest prevalence of undernutrition (wasting, stunting and underweight) among children in Pakistan (Box 2) and the highest number of households who are food insecure (72%; compared to 58% nationally.)¹⁸

The prevalence of anaemia for both mothers and children is higher than the national average; zinc deficiency is slightly lower than national averages and Vitamin A deficiency is similar to the national average (Box 2). Only 9% of infants in Sindh are exclusively breast fed for their first 6 months of life as recommended by the WHO.¹⁸

Undernutrition		
status (%)	Sindh	Pakistan
Child		
Undernutrition (severe + moderate)		
Underweight	40.5	31.5
Stunted	49.8	43.7
Wasted	17.5	15.1
Micronutrient deficiencies		
Vitamin A	53.3	54.0
Anemia	73.0	62.0
Zinc	38.6	39.2
Mothers		
Vitamin A deficiency	46.7	46.0
Anemia - pregnant women	62.0	51.0
Zinc deficiency	44.5	47.6

Gender inequalities

Inequalities between men and women in Sindh are also higher than national averages.^{xx} In Sindh, women are more likely to be unemployed and less likely to be allowed to work for income; only a minority of women have bank accounts; nearly a quarter of women think that men have the right to hit women; women have very little autonomy within the household; men are served first during meals; girls are more undernourished than boys (reported in the Pakistan NNS¹⁸ – also see table 2 below).

2.3 Dadu District

Dadu District (approximately 7,866 square kilometres) is composed of four Talukas (Dadu, Johi, Mehar and Khairpur Nathan Shah), which are further sub-divided into 52 Union councils (UCs) with a population of 1.1 million people.⁵⁵ The main languages spoken throughout Dadu District are Sindhi, Siraiki, Urdu and Balochi. The district headquarter Dadu is connected with metalled roads to all *taluka* headquarters. The district is also connected by the railway network.

Dadu district is divided into 3 dissimilar areas: i) *Kach'o*, the semi-arid area nearby the mountainous (*Kohistan*) western part of the district, which is also included in this area; ii) *Pakko*, the barrage area where most towns

xx Sindh MDG report UNDP www.kz.undp.org/content/.../UNDP-PK-MDG-SindhReport-2012.pdf

are located; and iii) *Kacho*, the lowlands riverine area. Daytime summer temperatures are above 45°C; with night time temperatures remaining above 29°C. In winter, temperatures are relatively cooler, 24°C in the day and 5°C at night.

Dadu District was identified by the WHO as one of seven worst hit districts in Sindh Province in the 2010 floods, ⁵⁶ and subsequent floods have compromised recovery and rehabilitation. In 2010, 61% of the population (0.92 million people) were affected with a further 325,000 people in 2011 (National Disaster and Management Authority (NDMA))⁵⁷.

Livelihoods^{xxi}

The economy in Dadu district is largely agrarian; dependent on crop production and keeping of livestock and agriculture labour (Annex 1) and is highly vulnerable to future floods and shocks.

Income opportunities for poor and very poor households (about 68% of the population (33% very poor; 35% poor (ACF Household Economy Approach report 2013)) are constrained by lack of skills and capital. With limited access to land, a high proportion of very poor households (87%) are dependent on incomes from casual labour or self-employment; 90% of these households are reliant on the markets for food purchase. The very poor households do not meet daily energy intake requirements (1911 kcal/day instead of 2100 kcal/day). Diets (increasing quantities with wealth) largely consist of cereals and then potatoes, pulses and milk. All households have access to oil/ghee and sugar. All but the very poor have limited access to meat or fish. Sources of milk and meat come from goats (very poor), cattle (poor) and cattle/buffalo (better off groups). Other nonfood expenditures for the poorer households include for example, soap, salt, paraffin and money for grinding cereals. There is low expenditure on social services such as education and health (across all wealth groups).

Ninety two percent of the population in Dadu (regardless of wealth group placing) lives below the \$1.25 a day poverty threshold; only the 8% in the top wealth group live above this level. This means that the majority of the population is vulnerable to shocks but especially the poorer households, and there is a lack of alternative income sources. Coping strategies are limited in Dadu, thus reducing resilience to further shocks. The Government's Benazir Income Support Programme (BISP) was set up to provide the most vulnerable households (based on poverty score criteria) with a 12% annual income supplement. However, household coverage of the BISP in Dadu is still relatively low (about 30,000 households; less than 10% of the population)^{xxii}.

3. ONGOING OR PLANNED HUMANITARIAN INTERVENTIONS IN SINDH, PAKISTAN

3.1 ACF Pakistan in Sindh

ACF have been operational in Sindh province following a cyclone and floods in 2007. During this time, ACF were operational in Dadu and Kamber Shahdadkot Districts, assisting with building of latrines, water trucking, drilling of wells, hygiene promotion, and distribution of hygiene kits to 36,000 flood victims. Food security and nutrition surveys were also carried out in these areas.

Since 2009, ACF has been implementing integrated FSL/WASH programmes in Sindh Province (Thatta District), and in 2010 when flooding re-occurred, ACF responded in Thatta District with FSL/WASH responses, covering 400,000 people.

ACF Pakistan is currently supporting the Department of Health (DoH) in 41 UCs in Dadu (Figure 8) through a programme aimed at Women and Children/Infant Improved Nutrition in Sindh (WINS)^{xxiii}. WINS is a 4-year integrated FSL, WASH and nutrition programme (2013-2016), funded by the European Union (EU) and being implemented in collaboration with the Sindh Government (DoH) in response to the floods.

The WINS programme is being implemented in 3 districts with 3 different implementing agencies: ACF in Dadu (Annex 2), Save the Children in Shikarpur and MERLIN in Thatta. The WINS programme aims to improve the nutritional status of children and pregnant and lactating women in Sindh through: Community based

^{xxi} A HEA assessment was carried out by ACF in Dadu referring to the livelihoods reference period March 2012 to February 2013. http://www.wins.org.pk/background-information.html

^{xxii} Dadu District Health Sector Plan, http://fdsindh.gov.pk/sdssp/Health%20Sector%20Plan%20-%20ASP%20DADU.pdf ^{xxiii} Whilst ACF started off directly implementing nutrition and health programmes they are in preparation to 'step back' and start to hand over to the DoH – starting with a health systems strengthening workshop aimed at coordination and defining next steps.

Management of Acute Malnutrition (CMAM) programme, improved nutrition practices, food security and livelihoods, WASH and evidence based advocacy.

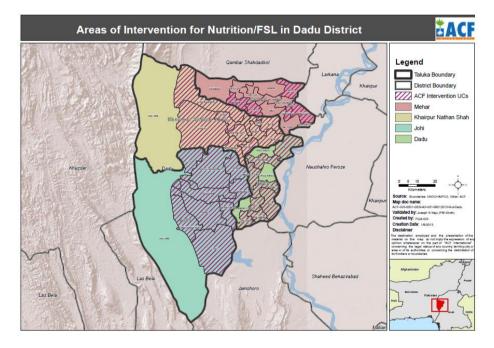
WINS is working towards achieving the four outcomes below:

- Treatment of children with SAM through government health institutions
- Improved practices related to preventing undernutrition with improved access to nutritious foods for infants aged 6-8 months
- Improved physical and financial access to micronutrient rich food through increased nutritious food production
- Lessons learnt and evidence based recommendations on effective interventions used at scale to inform social protection schemes and health service delivery

To achieve these outcomes, ACF are implementing a number of different projects in Dadu district (starting years in brackets):

- 6-month cash safety nets (Y1-2)
- Complementary food (fresh food) vouchers^{xxiv} (Y1-4)
- Kitchen gardens + cooperative marketing (Y2-3)
- Community-based small animal management (Y2-4)
- WASH infrastructure (Y2-3).

Figure 8: ACF WINS Intervention areas



All ACF programme participants are expected to attend behaviour change and communication (BCC) sessions by trained nutrition staff. Topics included are awareness of undernutrition; Exclusive Breastfeeding (EBF) during first 6 months; dietary diversity; hand washing and avoiding water contamination.

Whilst the design of the current ACF WINS programme ^{xxv} has been built on lessons learned during the humanitarian flood responses, the overall approach encompasses the transition from relief to recovery to resilience. Inclusion of government line agencies are being ensured at all levels, e.g. for FSL, line agencies are engaged for capacity building and activities to develop linkages between the government and community. The programme's approach is in line with the Sindh Nutrition Response Strategy (2011), Pakistan Integrated Nutrition Strategy (PINS) operational plan (2011-2012), and the EU Reference Document on Addressing Under nutrition (2010).

The design of the ACF WINS programme was influenced by a number of baseline studies: a Nutrition Causal Analysis (NCA), an IYCF Knowledge Attitudes and Practices (KAP) study, a SMART survey, a Cost of Diet (COD)

^{xxiv} These are given to discharged MAM children as a replacement for RUSF.

^{xxv} Women and Children/Infant Improved Nutrition in Sindh.

analysis, a Semi Quantitative Evaluation of Access and Coverage (SQUEAC) survey and a Household Economy Approach (HEA) assessment.

At the end of the first year of the WINS programme in 2013, ACF carried out a Rapid Socio-Cultural Assessment (RSCA) with the following aims:

- i) to better understand the communities ACF currently works and intends to work with
- ii) to acquire knowledge about the perception of the communities with regards to the underlying causes of undernutrition
- iii) to identify key features of the community that could (directly or indirectly) affect the planning and implementation of the WINS programme e.g. contribution to the development of a comprehensive BCC strategy to fit with the wider Community Mobilisation (CM) strategy adopted by ACF.

In rural Dadu, families live in households which are clustered together into villages (*goth*^{xxvi}). More than one family may live together in compounds which can have several caregivers of children. In urban areas, households are more typical of towns where *mohallas* or "neighbourhoods" are sometimes organised on a kinship basis and represent the basic unit. There may also be some nuclear family set up where just one family lives together. Family organisation is patriarchal whereby both males and females belong to their father's kin group.

Child acute malnutrition rates in Sindh Province have remained persistently high over the last 10 years¹² and especially so after the recent floods (Table 1). 50% of children are stunted (half of whom are severely stunted) and this level has persisted.¹⁸

ACF (since the start of the WINS programme) have an active Nutrition Information System (NIS) providing monthly GAM (MAM & SAM) prevalence. Based on this, the prevalence of GAM and SAM are as follows for July, August and September 2013: 14.7%, 17.6%, 19.0% (average 17.1%); 4.2%, 4.4%, 5.8% (average 4.8%). This information shows an increasing trend in acute malnutrition as the lean season advances.

Table 1: Prevalence of undernutrition in children 6-59 months (with confidence intervals in brackets) in selected areas in Dadu district (ACF surveys) 2007-2013

	Dadu District Nutrition survey results 2007-2013													
Indicators		Oct-Nov 2007	June 2008	Oct 2011	Dec 2012	Nov 2013								
WHO	GAM ¹	17.8%	28.3%	19.5 %	13.0%	12.6%								
2006		(14.8% - 20.9%)	(23.6% - 33.0%)	(17.6% - 20.6%)	(6.4% - 20.3%)	(8.0% - 19.5%)								
growth	SAM ²	3.2%	5.7%	5.3%	3.8%	1.8%								
standards		(1.9% - 4.5%)	(3.8% - 7.6%)	(4.2% - 6.6%)	(2.5% - 5.7%)	(0.7% - 4.2%)								

¹WHZ(<-2 Z-score or oedema);²WHZ(<-3 Z-score or oedema)

The ACF SMART Dadu survey results (Table 2 – children 6-59 months) shows that wasting is higher in girls than boys (although not statistically different); there were twice as many girls with SAM than boys.

It has been reported that in Pakistan boys are more likely to be taken to ACF treatment centres (OTP) than girls (personal communication from the ACF gender consultant who was carrying out a qualitative assessment during the REFANI country visit, June 2014). However, there is other evidence that shows no gender bias in treatment of a sick child due to the altruistic nature of Pakistani parents when their child is ill; although this is confounded by the geographic, socio-economic and demographic characteristics of the mother.⁵⁸ Treatment for undernutrition does depend on the understanding of what undernutrition is and the treatment options available, both of which have increased with the presence of the ACF programme (ACF Rapid Socio-Cultural Assessment 2013).

The NCA carried out by ACF⁵⁹ and a further cross-sectional quantitative analysis by Fazal et al⁶⁰ identified the following in Dadu as being important associated factors with the risk of undernutrition: low household income,

^{xxvi} *Goths* or villages may in turn be clustered into a *Deh* which is used as a technical revenue term/unit in rural Sindh - *Dehs* are then constitutive parts of Union Councils.

insufficient potable water, poor hand washing, inadequate care practices and limited knowledge of mothers, poor food security (access), poor dietary diversity and inadequate food intake of children.

Table 2: Prevalence of undernutrition (with confidence intervals in brackets) by sex in Dadu district (ACF SMART survey November 2013)

	All n = 506	Boys n = 268	Girls n = 238
Prevalence of global acute malnutrition (<-2 z-score and/or oedema)	(64) 12.6 % (8.0 - 19.5)	(31) 11.6 % (6.5 - 19.7)	(33) 13.9 % (8.2 - 22.5)
Prevalence of moderate acute malnutrition (<-2 z-score and >=-3 z-score, no oedema)	(55) 10.9 % (7.1 - 16.3)	(28) 10.4 % (6.0 - 17.7)	(27) 11.3 % (6.4 - 19.3)
Prevalence of severe acute malnutrition (<-3 z-score and/or oedema)	(9) 1.8 % (0.7 - 4.2)	(3) 1.1 % (0.4 - 3.5)	(6) 2.5 % (1.0 - 6.2)

3.2 The use of cash transfer programmes (CTPs) in Pakistan

CTPs are not a new concept in Pakistan. The first social security programme was implemented in 1954. Social safety nets in Pakistan fall into 2 categories; social security (targeting employed labour force and/or retirees e.g. old age pension) and social transfers/assistance (welfare initiatives aimed at poorest households/members of society). Examples of these can be found in Annex 3.

The Benazir Income Support programme (BISP) is a quarterly cash transfer given to some of the poorest households (and also includes special initiatives whereby cash is given for other reasons e.g. Waseela-e-Taleem – a conditional cash transfer (CCT) programme for the primary education of the children aged 5-12 years – conditional on the children going and staying at school).

Emergency CTPs

Emergency cash transfers were provided by the GoP to households affected by the earthquake (e.g. in 2005), bomb blast victims and Internally Displaced Populations (IDPs). In mid-2009, Mercy Corps launched a USAID/OFDA-funded CTP to address the immediate recovery needs of people displaced by military operations in North West Pakistan.

Flood response CTPs have been implemented since 2010 by many agencies working, alongside the GoP e.g. donor and multilateral agencies (The World Bank, DFID, USAID, WFP, Governments of Italy and Switzerland) and INGOs (e.g. ACF, Acted, Care, International Rescue Committee, Mercy Corps, Oxfam, World Vision, Save the Children).

Cash or vouchers

Voucher systems have already been used in Pakistan. Examples include the Creating Assets for Rural Women Programme (CARW)^{xxvii} and the Pakistan Emergency Food Security Alliance (PEFSA)^{xxviii}. Food vouchers have also been shown to increase immunisation coverage during the course of a study in Pakistan.⁶¹

ACF International has been implementing CTPs xxix since the late 1990s with the main focus on the treatment and prevention of acute malnutrition. Both cash and vouchers have been used including Fresh Food Vouchers (FFV) to increase access to fresh foods (vegetables, fruit, eggs, meat, milk and fish). FFV programmes have provided households with complete food baskets, or have been used to supplement staple foods with fresh micronutrient-rich foods. FFV programmes also support local markets and traders. The ACF FFV programme has been designed to encourage dietary diversity by providing small denomination vouchers to encourage purchase of specific food groups.

^{xxvii} (CARW) which primarily targeted vulnerable rural women in Balochistan, Sindh and AJK. This was a vouchers-forassets programme, with vouchers provided to participants as wage compensation for creating assets.

^{xxviii} ACF implemented a food voucher programme in Pakistan during 2010/11 floods. However, rather than have a specific nutritional objective the voucher had a generic consumption objective. The voucher programme was implemented following the provision of small business grants to vendors. The combined intervention was meant to increase both the local supply and demand for food.

^{xxix} For a fuller understanding of how CTPs interface with food security, nutrition, health etc. see literature review.

The choice of cash or vouchers should be guided by the country context (such as severity of food insecurity and functioning of markets but also include beneficiary preference as well as any gender-specific risks associated with different transfer modalities⁶²). They should also be designed to meet the desired changes required (e.g. nutritional objectives). In past programmes in Pakistan, women beneficiaries have expressed preference for vouchers, since they are more likely to have control over vouchers than direct cash transfers.⁶³ However, in other instances, CTs may be more flexible and amenable to respective needs.

4. JUSTIFICATION FOR THE STUDY

4.1Study justification

The WINS programme in Dadu provides an interesting case study opportunity for REFANI for a number of reasons:

• *High risk of wasting:* The two issues of interest here are the prevailing high GAM rates in the area, which are affected by a number of factors but which are worse during the summer lean period (e.g. food insecurity (access))^{xxx} and also the historical and continuing high risk of natural disasters.

ACF staff in Pakistan describes the situation in Dadu as a long-term protracted crisis with seasonal GAM spikes. There are 2 lean seasons: summer (June-August) and winter (Dec-Jan). The summer lean season has the larger impact on nutritional status where nutrition status is at its worst. During the winter lean periods, GAM rates have been recorded that are above internationally agreed cut-off points for defining an emergency. In recent years, there has been a lowering of rates of acute malnutrition, as would be expected in an area going from relief to recovery though rates remain unacceptably high.

- *Scalability:* Nutrition has become a prominent topic in Pakistan and the GoP is interested in aligning the current SSN (BISP) with the need to improve nutrition outcomes. Attention is being made to the transitioning of EU funded programmes into government programmes for longer-term benefits. The ACF WINS programme team has been working with the GoP BISP and the REFANI study hopes to provide evidence to support the importance of SSNs (including use of nutrition targeting criteria) for nutritional improvement as well as provide ACF a chance to further lobby the GoP on how better to engage with nutrition issues.
- *Funding availability and predictability:* The WINS programme is funded for 4 years until 2016. Whilst some of the programme interventions have already started (2013), the remainder are due to start this year (2014).
- *Interventions:* The cash safety nets were set up with BISP collaboration and the targeting was done using the same methods as the BISP i.e. poverty score card (PSC). Eligible households were given a one-off lump-sum (approx. Rs16-17000 equivalent to around Rs.1200-1500/month^{xxxi}) in the first year. The ACF HEA estimated that a locally appropriate diet for an average household (7) costs PRs15000/month. The CTP is expected to provide a top-up to cover the daily energy requirements (kcal) for the poorest households; the gap is about 10% for very poor households and 1% for poor households; the PRs1500/month CT is expected to cover this deficit.
- *Capacity and buy-in:* ACF has had a presence in the area since 2007. The country office is open to, and has the capacity to engage with a REFANI research study. Some of their own research interests converge with REFANI research questions, particularly around design issues of CTs such as timing and frequency as well as looking at complementary interventions implemented with CTs and cash versus vouchers.

Baseline data on the WINS programme has been collected and this could provide a good source of secondary information. ACF have an active Nutrition Information System (NIS) providing monthly screening data on the number of children with low MUAC (<12.5cm).

Other research in the area:

^{xxx} According to the Integrated Food Security Phase Classification (IPC) Dadu fits into 'Acute Food and Livelihoods Crisis' due to high GAM rates and food consumption gaps during the seasonal lean period ^{xxxi} Depending on Euro exchange rate

Dadu is becoming an important area for research which means there is a wealth of data being produced. Two important research programmes are;

- 1. The C-project to assess whether CMAM community case management of SAM is better if done by Lady Health Workers rather than NGOs (in terms of effectiveness, cost-effectiveness and coverage) Aga Khan University (AKU) is the research partner.
- 2. The PUR project is a cluster RCT with 4 arms covering areas with CMAM and implementing different water treatment programmes. The research partner is Johns Hopkins (funding to be determined; there is also discussion on-going as to whether to move it to a different district).

REFANI will need to ensure there is no overlap in the villages with this and other research as these research projects will be implemented at the same time as REFANI i.e. when diarrhoea is expected to be higher. REFANI will ensure testing of the current WINS programme effects rather than a new intervention.

5. AIMS AND OBJECTIVES

The overall aim of the REFANI project is to enhance the understanding of the mechanisms by which cash or voucher-based intervention packages work to reduce the risk of undernutrition in children 6-59 months of age and their mothers in emergencies. This aim will be achieved through conducting a series of comparative case studies in different contexts.

This study aims to test the effectiveness and the cost-effectiveness of different CTPs on reducing the risk of undernutrition in children 6-59 months and their mothers in Dadu District, Sindh Province, Pakistan. Specifically our primary objectives are to compare whether using seasonal unconditional CTs or voucher transfers has a greater impact on the reduction of wasting and anaemia in children 6-59 months compared to a comparison group that receives the standard WINS intervention only.

The CTPs will be either a seasonal CT which will be an unconditional (UCT) or a seasonal Food Voucher (FV) that can only be spent on specified food items with participating traders in selected markets. A third intervention will involve a CT with an amount double to the other CT intervention to compare the impact on nutritional status of different CT amounts (to be confirmed with extra funding and denoted within this document with the following symbol: with a *). The 'normal' UCT amount (PRs 1500) reflects the amount of the current BISP. However, it is unknown if this amount is enough to have a significant impact on nutrition status. The Cash PRs 3000 arm would provide double the amount of money and allow a comparison between 2 different amounts on nutrition status impact. This would be the first study carried out in a post-emergency setting and would not just inform programming in Pakistan but also the current global debate around amounts of cash transfer that impact nutrition status. Each intervention arm will be costed and the relative cost-effectiveness evaluated to explore the cost implications of the intervention modification and its effectiveness by outcome.

We do not assume that increasing household income *on its own* will result in an improved situation that favours good childcare and feeding practices, and behaviours protecting and promoting mother's and children's nutritional status. Other important drivers of undernutrition in Dadu^{xxxii}, aside from low household income, will be covered in the ACF WINS programme.

The guiding framework for the study will be adapted from a generic theory of change (TOC)^{xxxiii} developed to facilitate a common approach across all the REFANI studies . The TOC encapsulates the causal pathway framework between CTs and nutrition status, and this will be developed further during the early implementation stages to both fit the local context in which the ACF team is working in Pakistan and to include specificities for the pathway for Food Vouchers (FVs).

The Pakistan REFANI study will employ a mixed-methods approach to not only assess the overall impact of the CTP on child and mother nutrition status, but also to answer a number of questions identified as gaps in the evidence-base from the REFANI literature review

6. RESEARCH QUESTIONS [REDACTED]

^{xoxii} E.g. insufficient potable water, poor hand washing, inadequate care practices and limited knowledge of mothers, poor food security (access), poor dietary diversity and inadequate food intake of children.

^{xxxiii} Embargoed, pending future publication in peer-reviewed journals.

The Pakistan Study's main research questions revolve around examining how effective different CTP interventions are at reducing the risk of undernutrition. Additional research questions delve deeper into impact on the prevalence of anaemia, the improvement of ponderal and later gowth, recovery and the revention of readmission to treatment programmes, etc. A detailed account of the REFANI Pakistan Study research questions has been embargoed, pending future publication in peer-reviewed journals.

7. HYPOTHESES [REDACTED]

The Pakistan Study's primary hypothesis explores the link between the various CTP intervention control arms and the reduction in the prevalence of wasting. A detailed account of the REFANI Pakistan Study hypotheses has been embargoed, pending future publication in peer-reviewed journals.

8. ETHICAL CONSIDERATIONS

Ethical approval will be sort from the National Bioethics Committee in Pakistan, ACF International Scientific Committee and Aga Khan University Ethical Review Committee.

The study will be registered with the International Standard Randomised Controlled Trial Number (ISRCTN).

Consent will first be gained at the village level for village participation from village leaders. Written consent will be sought after explanation of the REFANI study and the requirements to implement the study to 1 year. Consenting villages will then be randomized to intervention or comparison group.

After the randomisation process has been carried out, households in the clusters will be approached for consent. Participants will be those who give informed consent after understanding the requirements of, and their participation in, the study (written, or orally in the case of illiteracy). The process of selecting households after the randomisation process could result in selection bias⁶⁴ and all attempts to encourage households to participate will be made such as involving the villages and village leaders with community mobilisers in the sensitisation of the study and the randomisation process. We also hope to maximise compliance by exclusively enrolling all children 6-48 months from poor and very poor households. However, participants are free to leave the study at any point and without having to give a reason.

We considered ethical concerns due to the exclusion of other non-eligible households.⁶⁵ However, we concluded there to be none since food security is not considered a problem for these households (in the same terms and under 'normal' circumstances) and all these households still have access to the ACF WINS programme (including the screening undertaken by ACF for CMAM referral purposes).

We also considered potential ethical concerns from using a comparison group. However, all children 6-59 months have access to the ACF WINS programme. Also, whilst we do not expect the CTP interventions to have any negative effect, the evidence for the use of CTPs on nutrition impact is scant and as yet has not been shown to comprehensively show an impact on nutrition status. Also within the time limit of 6 months, it is not expected that the study would have to stop early.

9. METHODS [PARTIALLY REDACTED]

As a complex public health intervention (i.e. one that has a high causal density^{xxxiv}) this study has adopted a theory-based approach, where we will use both summative and formative methods (sometimes referred to as a programme theory approach^{xxxv}) to determine the impact (the what) and the processes involved^{xxxvi} (the how), as well as the costs involved from a cost-effectiveness analysis (CEA). Recognition is growing that there is a need to understand this complexity if future intervention development is to be informed, or efforts to apply the same intervention in another setting or population are to be made.

xxxiv Between CTPs and nutrition status there is a complex framework of numerous mediating and moderating factors making it difficult to know with any predictability how a programme will work – unless these factors are clearly unpacked.
xxxv Programme theory in this case refers to the mechanisms that mediate between the cash and nutrition status to determine the processes which may either hinder or promote acute malnutrition through CTPs.
xxxvi These processes may either hinder or promote good nutritional status through CTPs.

Impact will be assessed through a pragmatic longitudinal cluster randomised controlled trial (cRCT). It is pragmatic in that it can be used to inform decision making in practice by asking the question "Does this intervention work under usual conditions?" whilst retaining the rigour of randomisation (thus eliminating selection bias) and retaining the characteristics of normal conditions. This study is longitudinal and will follow the same group (closed cohort) of selected clusters of eligible households with children (6-48 months)^{xxxvii} in each arm over one year. Baseline data will be collected before randomisation procedures. A counterfactual will be included and will represent the 'standard care' arm whereby villages will receive the interventions delivered by the WINS programme only. These will be the same components of the WINS programme that the intervention groups receive.

Whereas quantitative data will tell us about different measures of effect, qualitative data will tell us about the subjective experiences, understandings, effects and impacts. In this way, the qualitative data will be used to augment the quantitative data in data collection tool design (e.g. by informing content and rational piloting) and help to understand any associations found (or not) within quantitative analysis (through triangulation, and complementarity).

As well as this, it is important to understand how and why the different interventions were successful (or not) if results are going to be transferable across different contexts. For this, a process evaluation will be carried out to help understand the different interventions themselves by unpacking the causal framework and determining the importance of mediating factors, understanding the context (the social, political and organisational setting within which the intervention is set) and evaluating how the context interacts with the interventions.⁶⁶ A process evaluation is also necessary for understanding where the intervention implementation may have been a help or a hindrance to the achievement of expected outcomes. The process evaluation will be adapted from the framework developed for cRCTs proposed by Grant et al⁶⁷ (Annex 4).

The Pakistan study will use several different methods to assess overall cost cost effectiveness and resource use of the CTP interventions, using a societal perspective.

A detailed account of the REFANI Pakistan Study methodology – including information on participant targeting, eligibility criteria, interventions, outcomes, sample sizes, randomisation, data collection, and statistical analysis – has been embargoed, pending future publication in peer-reviewed journals.

10 STUDY MANAGEMENT

10.1 Staffing

The study will be managed by the ENN PI, with support from the PM, and overseen by the REFANI management group. Data collection and supervision of the study team will be carried out by the ENN SC who will be in situ for the duration of the project. The ENN SC will receive regular supervision from the ENN PI.

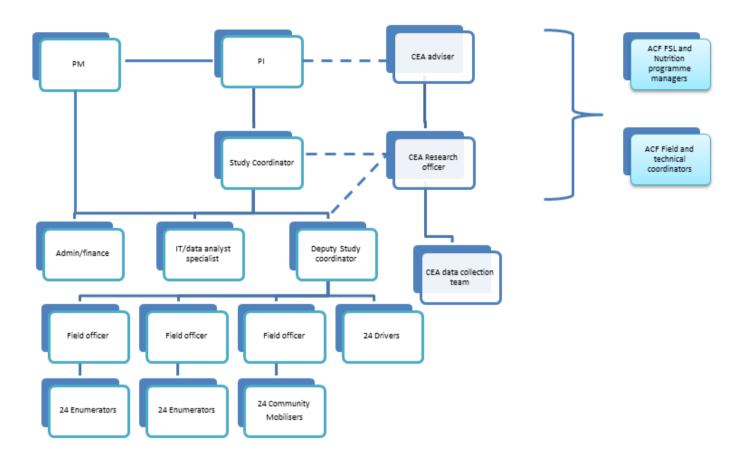
It is important to build and maintain strong links between the research and the implementation of the intervention. There will be a number of reporting lines established early during implementation. The ENN PI and SC will work closely with the ACF FSL and Nutrition programme managers during the set-up and planning phases of the research to coordinate research and implementation activities. The ENN SC will liaise directly and regularly with the ACF Field and Technical Coordinators during the implementation of the intervention.

The Cost Effectiveness Analysis staff will work closely with the Islamabad based Country Financial Comptroller, and her staff in Dadu base. The ENN SC and cost-effectiveness research officer and team will be supported by Chloe Puett, ACF CEA advisor.

The team will be assembled in Pakistan and the structure is outlined in Figure 12.

Figure 9: Organogram of staff needed for primary data collection

xxxvii To avoid having in the sample children with partial exposure and follow-up times; and to ensure no child exceeds 59 months at the end of the follow-up period.



Training and piloting

All data collection tools and instruments will be piloted prior to study baseline data collection. Data collection tools will be developed with UCL to ensure complementarity, although tools will be made country specific during set-up and piloting. Piloting aims to:

- ensure that research questions work in the field, that nothing is missing (or not needed) and the translations (and back translations) have been done correctly
- ensure that methods are appropriate and troubleshoot any problems early (e.g. use of HaemoCue analysers)
- ensure that the enumerators are fully versed on what they are to do and why; and to be able to explain to prospective study participants
- train enumerator teams and learn from their practical experience of fieldwork to improve the data collection tools
- produce accurate manuals and protocols for data collection
- identify and begin to strengthen the skills enumerator teams will need in carrying out REFANI research
- initiate, build and maintain positive team dynamics and mutual respect
- ensure that data collection systems are in place

10.2 Roles and Responsibilities

The roles and responsibilities of the REFANI staff are in the general REFANI toolbox (Annex 5 Human Resources plan).

The specific responsibilities of all the stakeholders are described in Table 4:

- The *Responsible (R)* role identifies who is responsible for directly carrying out the work. If an activity does not have at least one responsible role, then this suggests that the activity will not get done. If there is more than one responsible role, then there could be an overlap of work.
- The *Accountable (A)* role identifies who is accountable for specific parts of the project. If there are multiple roles which are accountable, there may be a delay in decision making or unclear responsibilities.

- The *Consulted (C)* role identifies who is to be consulted for decision making. If there are many consulted roles, there may be a delay in decision making due to the number roles consulted prior to making the decision. If there are no consulted roles, this may also indicate a problem in decision making.
- The *Informed (I)* Role identifies who needs to be kept in the loop and informed of the progress. If there are many informed roles, there may be some communication problems underlying the process. If there are no informed roles, this may also indicate a communication problem.

Level	Who	Data Collection	Analysis	Interpretation	Supervision	Training	Feedback
1	Enumerators	R	Α	Ι	С	С	Ι
2	SC	Α	С	Α	R	R	R
2	CEA Research Officer	R	R	R	R	R	A
3	CEA Advisor	С	С	С	Α	Α	Α
3	PI	С	R	R	Α	Α	Α
4	Management group & PM	Ι	Ι	С	Ι	Ι	С

Table 3: Specific responsibilities

10.3 Risk Management

Risk Management Matrix (separate attachment)

Main Risks to the research project include:

- a. *Natural hazards:* Whilst there is a low risk of flooding this year (2014 Pakistan Meteorological Department), any rainfall may still cause problems as the infrastructure is inadequate to deal with excess water. WFP and FAO have been involved in de-silting drainage canals (through SIDA funding) but it is unknown to what extent this will prevent future flooding. There is some concern for next year as the natural cycle for the heaviest monsoon rains is 5 years the floods in 2010 fell within this cycle.
- b. *Accessibility:* This is not considered a problem even in rainy periods.
- c. *Security:* Dadu is considered to be relatively safe although this does not preclude random attacks that may occur. Travel to Dadu is via Karachi, itself subject to periods of high level insecurity.
- d. *Corruption or fraud:* This is always possible with CTPs. ACF have established a good tracking system for vouchers which could be used if mobile phones are used.
- e. Failure to obtain donor funding for planned intervention
 - Mitigation strategy:

ACF has received funding for four years under the EU-WINS programme for implementation of a variety of activities, including complementary food vouchers, social safety net cash transfers, small animal health management, micro-gardens, cash for work, etc. The proposed study was first introduced to the Pakistan Country Director and other Mission Staff in June 2014; close communication will be maintained throughout the finalisation of the study protocol to ensure that the necessary funding will be available.

- Contingency plan: In the event of limited funding, trial arm 4 will be dropped and a focus will be placed on arms 2 and 3.
- f. Incoherent messages from FDGs for societal cost

Given the integration of CEA questions into the ongoing cohort data collection, the sample size will be sufficient for the cost-effectiveness analysis. For focus group discussions, if the messages given by communities are not coherent or conclusive, we will add additional focus group discussions to confirm data up to a maximum of double the number of planned discussions (i.e. 8 per study arm).

10.4 Costs

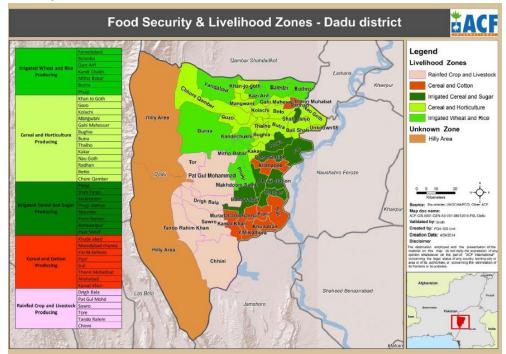
A budget (including also for the contingency study) has been prepared based on discussions between ENN and the ACF Pakistan staff and is included in the inception phase report.

10.5 Timetable

Table 5 illustrates the timing of the different study.

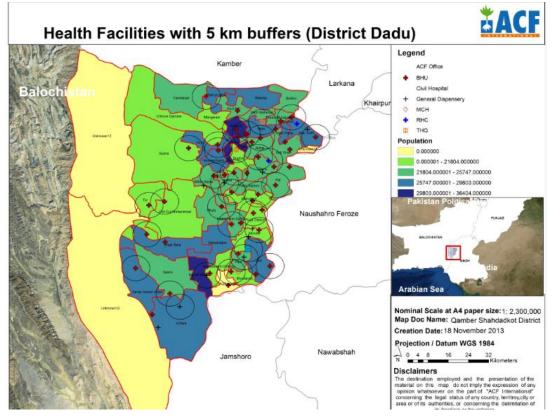
Table 4: Timeline of REFANI Pakistan country study

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Year							2015				2015						2015/6																																																							
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Planning																																																																								
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Data collection tools development			Х	Х																																																																				
Translation and back translation quests				Х																																																																				
Study set-up																																																																								
Pilot & acceptability tests					Х	Х	Х																																																																	
Recruitment of study team and training/piloting							х	Х																																																																
Secondary data																																																																								
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Analysis/reporting										Х	Х	Х				Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х	Х																																												
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Analysis/reporting										Х			Х				Х			Х			Х	Х	Х	Х	Х	Х																																												
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Annex A: Food Security & Livelihood zones - Dadu District

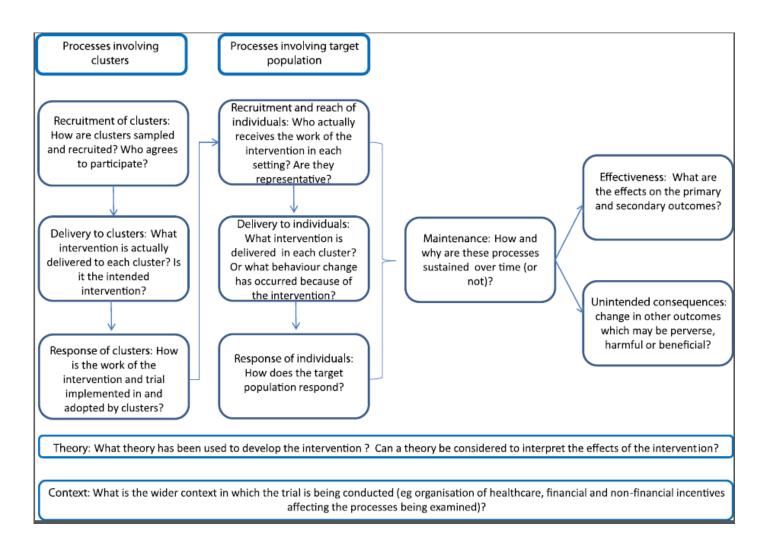
Annex B: Location of DADU and intervention areas



Annex C: Current Social Safety Net Programmes in Pakistan

- Bait-ul-Mal programme 2 main schemes:
 - Food Support Programme (FSP)
 - Individual Financial assistance including assistance for health and education e.g. child support programme (conditional cash transfer—on enrolment in school)
- Guzara (subsistence) funds of the Zakat fund a monthly cash transfer of PKR
 500 paid out to eligible Muslims in poverty known as the *Mustahiqeen* (deserving needy)
- Old age pension
- Tameer-e-Watan provides temporary employment to workers through labour intensive construction projects in the public sector
- People's Rozgar initiative gives access to subsidised credit to unemployed youth for starting their own business
- Female school stipend pilot programme in Punjab
- Micro-finance and micro-insurance programmes that fall under the social protection field
- Small loans for income generation provided by NGOs

Annex D: Framework model for designing process evaluations of cRCTs



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