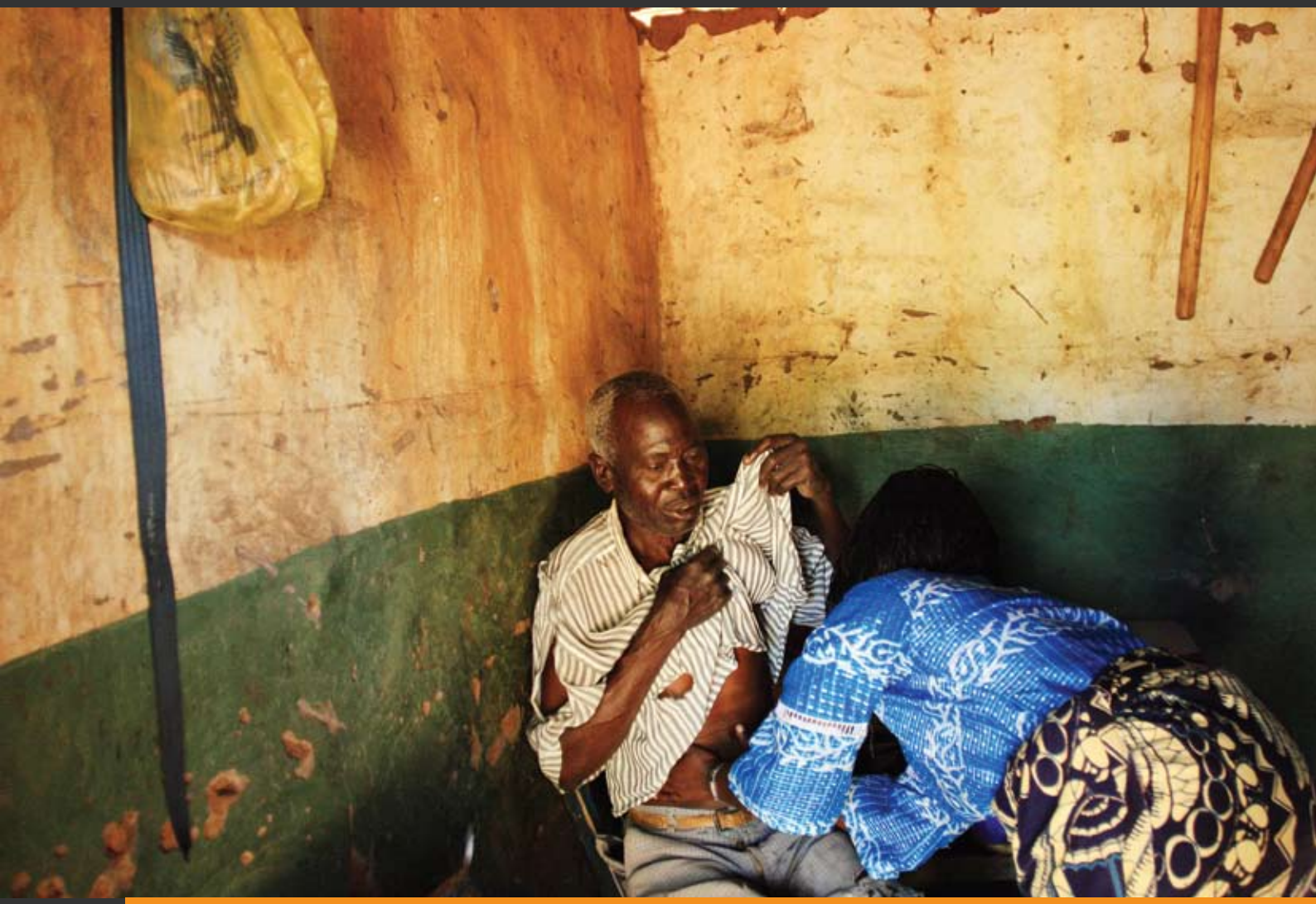


ADULT ART AND NUTRITIONAL SUPPORT

ADULT ART AND NUTRITIONAL SUPPORT

The scale up of ART in Malawi is being successfully implemented. By the end of June 2007, there were 109 facilities in Malawi in the public health sector delivering ART free of charge to HIV-positive eligible patients, plus 37 facilities in the private sector delivering ART at a subsidised rate. Of those who died, 66% died in the first three months of initiating therapy. It is unknown whether this is due to poor nutritional status, or opportunistic infections that are difficult to diagnose in resource limited settings.

In Malawi, most patients who start ART, both children and adults, do so when they have reached an advanced stage of HIV. A substantial number of these patients have poor nutritional status, which has shown to be correlated to high mortality in patients starting ART, but until recently there was no nutritional treatment for malnourished adolescents and adults available in Malawi. Integration of nutrition care, aiming both at the prevention and treatment of malnutrition, into HIV services is needed and can have a synergetic positive effect on the lives of HIV infected people.

Programmes addressing malnutrition in Malawi have mainly targeted children under 5 years of age. Despite the reduction in the incidence of malnutrition in developed countries with the introduction of ART, most research conducted on ART has involved well nourished food secure population groups, and recommendations are based on these findings. More information is needed about the efficacy and effects of antiretroviral drugs on malnourished populations.

As evidence has previously shown, patients starting ART often experience weight gain, an increase in appetite, and a reduction in the incidence of diarrhoea and other infections. Many physicians have anecdotal evidence of weight recovery in severely malnourished patients starting ART, but observational studies of groups of patients with wasting who initiate ART have shown inconsistent weight recovery[46]. In many patients, however, wasting and weight loss do continue to occur.

With funding from a UN consortium led by the World Food Programme, the ACF International Network conducted a pilot project in six ART sites between June and December 2005. The project looked at the implementation of therapeutic feeding at ART sites and the effects this had on the outcomes for patients.

Implementation

Patients starting ART were assessed for height, weight, and presence of bilateral pitting oedema. Pregnant women were assessed using MUAC.

Admission Criteria

Severe malnutrition				
Adults			BMI<16	Presence of bilateral oedema
Children and adolescents	MUAC <11cm	W/H <70%		Presence of bilateral oedema
Pregnant and lactating women	MUAC <19cm			
Moderate malnutrition				
Adults			BMI<17.5	
Children and adolescents	MUAC 11-11.9cm	W/H <70%		
Pregnant and lactating women	MUAC 19-21.9cm			

All patients were starting an ART regime of the fixed dose combination tablet of Lamivudine (3TC), Stavudine (D4T), and Nevirapine. Information was also collected on treatment adherence, ability to work, WHO stage of clinical disease, and quality of life.

WHO Clinical Staging of HIV in Adults and Adolescents

The WHO clinical staging system for HIV/AIDS uses clinical parameters to guide clinical decisions in the care and treatment of PLWHA. It was developed in 1990 and designed for use in resource-limited settings where access to sufficient laboratory facilities is not often available. It has proved its worth both at primary care level and in referral facilities.

Primary HIV infection	Asymptomatic
	Acute retroviral syndrome
Clinical stage 1	Asymptomatic
	Persistent generalized lymphadenopathy
Clinical stage 2	Moderate unexplained weight loss of less than 10% of total body weight
	Recurrent respiratory tract infections
	Herpes zoster
	Angular cheilitis
	Recurrent oral ulcerations
	Papular pruritic eruptions
	Seborrhoeic dermatitis
	Fungal nail infections of fingers
Clinical stage 3	Severe weight loss >10% of body weight
	Unexplained chronic diarrhoea for longer than one month
	Unexplained persistent fever
	Oral candidiasis or oral hairy leukoplakia
	Pulmonary tuberculosis diagnosed in the last two years
	Severe presumed bacterial infections
	Acute necrotizing ulcerative stomatitis, gingivitis or periodonitis
Clinical stage 4	HIV wasting syndrome
	Pnuemocystis pneumonia
	Recurrent severe bacterial pneumonia
	Chronic herpes simplex infection
	Oesophageal candidiasis
	Extrapulmonary TB
	Kaposi's sarcoma
	Central nervous system toxoplasmosis
	HIV encephalopathy

Adapted from WHO, 2005[47]

Initiation of ART is done according to the Malawi national guidelines. In adults and adolescents the following eligibility criteria are used:

HIV positive patients that understand the implications of ARV therapy plus one of the following:

- WHO clinical stage 3 or 4
- CD4-lymphocyte count <200
- WHO clinical stage 2 with TLC <1200

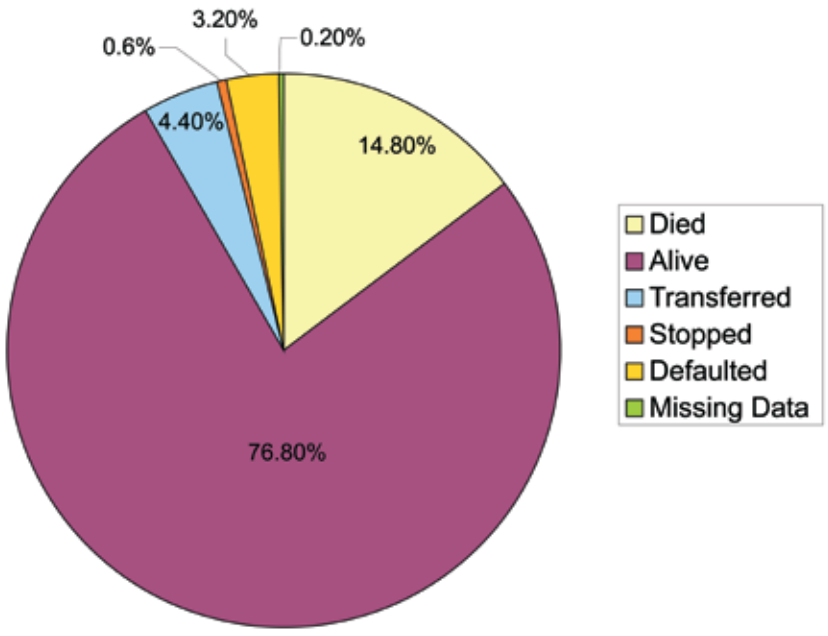
Patients with severe malnutrition were given a therapeutic ration of locally produced ready-to-use therapeutic food (RUTF) of 2600 kcal/day, and patients with moderate malnutrition were given a supplementary ration of corn soya blend (CSB) and oil of 1500 kcal/day. All patients were given nutrition counseling. Counseling was performed on a group and individual basis. Patients received counseling on different visits to provide continuity and not overload them, and to evaluate effectiveness of previous counseling sessions.

Data on quality of life was collected in two sites using the MOS, HIV and health questionnaire was used, with some additional questions. This consists of 35 questions which assess ten dimensions of health-related quality of life including general health perceptions, physical functioning, role functioning, pain, social functioning, mental health, energy, health distress, cognitive functioning and quality of life.

Results

A total of 1,244 patients started ART between the period July to December 2005. The mean age was 35.8 years. Patients responded well to ART, with few patients experiencing side effects, and adherence to the medication very high (above 95%). From the total cohort, 76.8% of patients were alive and on ART by month four, and 14.8% of patients died. 4.4% of patients were transferred, 0.6% stopped, 3.3% defaulted and 0.2% of data was missing. From the 14.8% of patients that died, 68% of patients died within the first two months.

Figure 8 Results from ART treatment

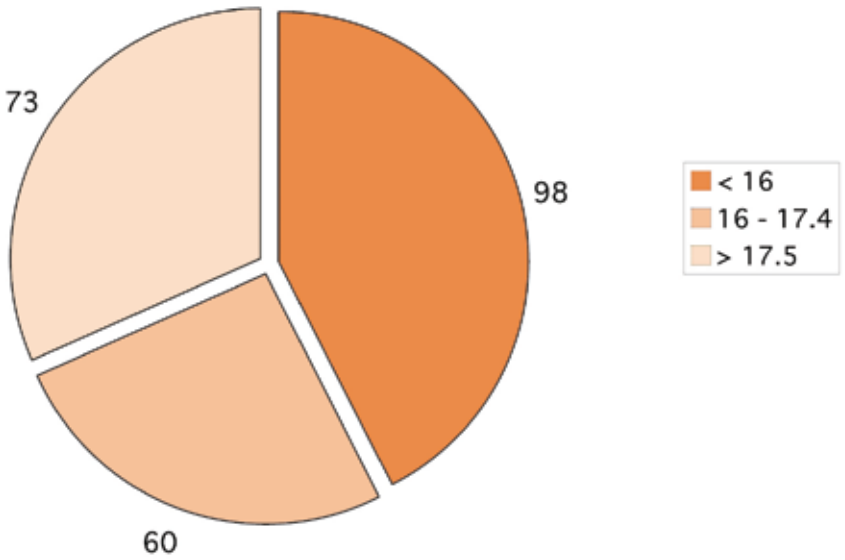


Copyright: Malawi MOH HIV Unit [48]

BMI data was available for 231 patients. 98 patients were recorded as having a BMI <16 indicating that they were eligible for therapeutic rations. 60 patients were recorded as having a BMI of 16 – 17.4 and therefore eligible for supplementary feeding rations and 73 patients were recorded as having a BMI over17.5. Within this group 34 patients presented with bilateral oedema.

Of those with a BMI>17.5, 27% of patients actually had a BMI <18.5, indicating they are at risk of malnutrition.

Figure 9 Number of Patients per BMI range from ART sites Malawi June-September 2005



The mean weight gain was higher in those patients with a BMI higher than 16 who were significantly more likely to gain more than 5kg by the fourth month than patients with a BMI below 16. A significant number of patients in the at risk group actually experienced weight loss. 50% of patients classified as severely malnourished with a BMI<16 died.

Approximately one third of patients from both severely malnourished and moderately malnourished patients died. In total, 34 patients were recorded as having oedema and therefore under this pilot programmes protocols were classified as being severely malnourished. Those patients with oedema had a significantly increased mortality, as did patients with clinical stage 4 disease.

From the quality of life questionnaires, under general health perceptions, patients receiving food support were more likely to view their personal health as poor. They reported more pain and low physical functioning with more problems in continuing work and other daily activities.

Patients who were not malnourished were more likely to have more energy and less problems with cognitive functioning in terms of concentration, reasoning and remembering than patients receiving food support; however they were also likely to feel more nervous and depressed and have a sense of despair and discouragement due to ill health than those receiving food support. This could possibly be related to the food crisis in existence at the time this programme was implemented.

Discussion

There are many limitations to this study. The programme was designed as a pilot project not as a research project, so the staff implementing the project had multiple responsibilities affecting the level of time and commitment that they had for the programme. As a result of this, not all information was recorded consistently, and it was not always of the highest quality. Due to more time spent on malnourished patients, height data is not available for the majority of patients that did not receive any food supplementation. There may also be limitations to the quality of life component of the programme due to translation and variable intervals between starting ART and conducting the questionnaires. However, there are many useful lessons that can be learned from the study.

One of the objectives of the pilot programme was to make recommendations on the guidelines and appropriate indicators to be used in the scale up of such a programme. Previous to this pilot there has been very little published on the use of appropriate indicators to use for a programme such as this one. A paper by C-SAFE[49] suggests the use of the following indicators for ART programmes: BMI, percentage of weight change, treatment adherence, risky coping strategies, quality of life, and need for caregivers. They point out that anthropometric indicators are useful components to measure the impact of food assistance, but used in isolation would not provide the level of understanding needed to assess a targeted food aid programme and could be potentially misleading. They can provide information on nutritional status and be helpful in assessing disease progression, but need to be interpreted in context[50].

Lipodystrophy is a condition in some people on ART that causes changes in the metabolism and body fat distribution, often presenting in wasted limbs and centralised body fat. MUAC was used in pregnant and lactating women in this programme but may be an indicator of limited use for future monitoring in light of issues of lipodystrophy. This pilot has not collected enough data, to make recommendations on MUAC but it is important to recognise the need for future studies looking at the use of MUAC as an indicator of malnutrition in a population group prone to lipodystrophy. Further research will need to be conducted on this, incorporating examination of skin fold thickness and handgrip dynamometry which is a tool used to assess a patient's muscle strength.

During implementation, nurses and clinicians and the HSAs implementing the programme expressed concerns about the at-risk groups not receiving treatment. This is evident in the number of patients in the at-risk group (BMI 17.5-18.5) that actually lost weight. Nutrition interventions at late stages of disease may not be as effective as those in the early stages. Research by the University of Carolina (UNC) in Malawi supports this as its showed that a BMI <16 was predictive of high mortality (50% of patients died within 6 months of starting on ART[51]). In terms of mortality and BMI there was little in the way of statistical significance in this pilot programme although the number of malnourished patients who died was high. The incidence of oedema however was significantly associated with mortality. It is necessary to further examine the appropriateness of oedema as an indicator of severe malnutrition in this patient group. It is likely that oedema in this patient group could be more indicative of a medical complication and requires more detailed assessment by a clinician to try and determine the cause.

Mortality in the cohort was higher in the first two months. This is consistent with national statistics and previous research findings. Patients starting ART in resource poor settings have shown increased mortality rates in the first months on therapy, compared with those in developed countries[52].

Concern was raised in many of the sites regarding the need for the use of clinical condition as an entry criterion to include patients who are very sick but do not meet the anthropometrical entry criteria.

Lessons learned

Following the implementation of this programme, some recommendations can be made. It is worth noting once again that this pilot programme was implemented by MOH staff in MOH centres with some external support from the ACF International Network. Implementing staff had high work loads already; monitoring and evaluation indicators for a programme such as this on a large scale need to be simple, efficient and kept to a minimum. While it is true on the larger scale that indicators should be restricted to the most essential and effective measures such as anthropometric and outcome indicators, this pilot programme and other literature highlights the need to investigate further the role of oedema and medical complications, lipid levels, and skin fold thickness to determine the true effects of nutrition supplementation.

In terms of the counseling tools and supporting materials, feedback received from staff using the tools provided for nutrition education and counseling sessions indicated the need for specialised materials for IEC. The main points emerging were the need for less text and more illustration. The nutrition education component of the programme was highlighted as essential to sustain long term nutrition status. It is neither practical nor possible in a resource limited setting such as this one, to neglect to provide long term solutions to maintain good nutrition. Increased focus could be placed on the nutrition counseling within the programme in order to improve the long term sustainability of the programme. Supportive materials such as meal planners could be included in the kit, and the kit itself reviewed to include less text, more illustrations and translation to Chichewa. Cookery demonstrations and methodology similar to that used in the hearth model should be adopted, or linkages made to initiatives using this model.

With the experience and lessons learned gathered during this pilot, the ACF International Network is supporting the MOH on the scale-up of the nutritional care programme to 60 ART sites. At their request, the ACF International Network will continue to give technical support concerning the implementation of the nutrition care and monitoring at ART sites.

Practical methodology to treat inpatients needs to be developed and implemented alongside the national scale-up, with all inpatient treatment linked with outpatient services for effective follow up care. Towards the end of the pilot the guidelines underwent a review based on some of the findings from this programme and including inpatients. This revision was urgently needed to provide clarity and consistency in the guidelines, but it still remains an interim version needing further review. The guidelines now include inpatient treatment using F75 and F100 as well as RUTF as the programme extends to treating inpatients. Some of the admission and discharge criteria have also been changed. The use of kwashiorkor as an independent indicator of severe malnutrition has been removed and now needs to be assessed by a clinician and combined with a low MUAC. Within these guidelines, monitoring and evaluation and reporting formats have been adapted from the pilot programme. These will need to be implemented at a national level and assessed for their appropriateness.

There are many challenges to the effective implementation of a programme such as this one. Human resources have been the main constraint to the programme. Heavy work load, high turnover of staff, and a lack of confidence amongst staff all have a negative impact. With regard to supervision, the pilot has demonstrated that effective supervision and monitoring of the programme is imperative for the successful implementation and early identification of misunderstanding of the protocols and effective treatment of patients. Lack of clinic and storage space is also a problem for quality of services and motivation of staff.

Participation from the start of district health officers and district nutritionists is essential to understanding and supporting the programme. Where possible clinic staff responsible for consultations should also be provided with a short training on the protocols in order for them to be able to provide support and advice where needed.

There is a need, where structures exist, to make links with community home based care (CHBC) in order to follow up on defaulters and to extend the programme to the community. It is likely that despite decentralisation, the most vulnerable do not present at ART clinics. Transport has been identified as a challenge in many of the sites and links with CHBC may prove to reduce this burden. The prevention of nutrition deterioration and promotion of positive living through innovative community programmes such as food diversification, low labour technologies and income generating activities can be integrated within community HIV programming and linked to facility based care, in order to try to reduce the incidence of malnutrition.

Conclusion

There are still many challenges when looking at early mortality in patients associated with low BMI. A high number of patients are wasted at the point of presenting at ART clinics. Interventions are needed to identify patients at an earlier stage of malnutrition to prevent wasting, delay the need for treatment or improve treatment outcomes. This may include providing nutrition support interventions to the at-risk group or in earlier clinical staging. In terms of research there are many areas which require further investigation including the impact of nutrition supplementation at the earlier stages, and the effects of nutrition supplementation on lean body mass and lipid levels. Further clinical evidence such as urine sampling and haemoglobin levels may help in determining nutrition and HIV associated oedema.