2.0 Methodology

2.1 Study setting
Malawi is a landlocked country in southeast, sub-Saharan Africa, bordered by Zambia, Tanzania, and Mozambique. Malawi is separated from Mozambique and Tanzania by Lake Malawi, a large freshwater lake which forms much of the eastern border of Malawi. Malawi has a subtropical climate, with a rainy season from November until May and a dry season from May until November. Twenty per cent of the land in Malawi is arable, with less than two per cent in permanent cultivation (CIA, 2009). Malawi is composed of three regions: the northern, central and southern region. These regions are further divided into 28 districts. Lilongwe is the capital city (see figure 12).

Malawi is one of the world’s poorest, least developed and most densely populated countries. Agriculture accounts for more than one-third of gross domestic product and over 90% of export income. Tobacco, tea and sugar processing are the main industries. Although Malawi’s economy is growing rapidly, with 9.7 per cent growth reported by the International Monetary Fund (IMF) in 2008 (Reuters, 2009). Malawi continues to be dependent on international donors, notably the IMF and the World Bank. The population of Malawi is growing, at an estimated rate of 2.4 per cent per year (CIA, 2009). The population of Malawi was estimated in 2007 to be 13,187,632 (Malawi, 2007). Malawi’s population is predominately rural, with less than 20 per cent of people living in urban areas. This is continuing to shift, however, with the country becoming more urbanised (Malawi, 2007).

Malawi was colonised by the British in 1891, and gained independence in 1964. Upon gaining independence Malawi was ruled by Hastings Banda in a one party state for 30 years. During his time in office Banda did not tolerate opposition, and enforced strict codes of conduct within Malawi. For example, men were required to have short hair and women were required to wear skirts or dresses with a length below the knee, with no miniskirts or trousers permitted.

Malawi now has a democratically elected government and a multi-party system. The president during this research project was President Bingu wa Mutharika, who was
elected in 2004. Official dress codes have been overturned, and people now speak more freely when criticizing the government. Malawi remains, however a conservative society. Most men continue to have short hair and most women continue to wear long skirts and dresses. Malawi is a hierarchical society and in the work setting most employees speak with deference to their supervisors. In the home, most decisions with financial implications are made by men, while most decisions regarding childcare are made by women (Bandawe & Kabwazi, 2003; Lee, 2002).

Figure 12: Map of Malawi
Source: CIA world Fact Book.

The MOH Malawi is by far the largest provider of health services in Malawi, followed by the Christian Health Association of Malawi (CHAM) (Malawi, 2007). All
government health services are free, while CHAM charges a small fee for service at its facilities. Maternal and child health services, including nutritional rehabilitation are, however, free at CHAM sites.

At the outset of this research, Malawi had 96 nutrition rehabilitation units. Forty-eight of these were supported by Action Against Hunger, UK, assisting in training, capacity building, supplies and implementation. MOH Malawi brought in a national programme of integrated community and facility-based care for the treatment of serve malnutrition during 2006. The roll out of this community-based programme was designed so that it would not interfere with the research project, as the study enrolment ended before the community-based care began in the study sites.

The Ministry of Health depends on international organizations for programme support, and due to the cost of programmes, donor fatigue is reported to be a problem. Malawi has a clearly defined system for responding to malnutrition, involving food security and nutrition surveillance for early response, along with established therapeutic and supplementary feeding programmes with monitoring, supervision and reporting mechanisms in place.

Figure 13 shows a marked seasonal pattern of admissions to the nutrition rehabilitation programme reported at the monthly meeting of the national targeted nutrition programme, a group led by the Ministry of Health to coordinate and report on the national nutrition response. The reduction in NRU admissions during 2007 may be partly related to the increasing treatment of malnutrition at the community level in Malawi, using RUTF.
Malawi has a full set of national guidelines in place to guide nutritional rehabilitation at both the facility and community level (see table 3).

Table 3: Guidelines for the treatment of SAM in Malawi

<table>
<thead>
<tr>
<th>Country</th>
<th>Existing practice guidelines</th>
<th>Guidelines in development/Interim guidelines</th>
</tr>
</thead>
</table>
| Malawi  | 1. Inpatient management of severe acute malnutrition (interim guidelines)  
2. Guidelines for managing moderate, acute malnutrition (interim guidelines) | 1. Interim guidelines for managing acute malnutrition through community-based care  
2. Interim guidelines for the management of acute malnutrition in adolescents and adults |

Action Contre la Faim was established in 1979 by a group of French doctors with a goal of ending world hunger. The Action Contre la Faim International Network (ACFIN) works in 30 countries across Africa, the Americas and Asia. ACFIN operates as a network of five headquarters in Paris, London, Madrid, Montreal, and New York. In 2003 the London office (Action Against Hunger UK, AAH UK) was managing the project in Malawi. As part of their country programme AAH UK had a nutrition project. This project involved supporting the MOH and CHAM at 48 of the 96
NRUs across the country with training, monitoring and evaluation, and supply of therapeutic foods.

There were reports coming from the NRUs in Malawi of high mortality. Children with SAM within the NRUs were not being tested for HIV, however HIV was suspected in many of the cases. These reports in 2003 led to the need for a programme of research to investigate the impact of HIV on children with SAM being recognised.

2.2 Study sites
This study was carried out at two MOH and one Christian Health Association of Malawi (CHAM) NRUs in Lilongwe district, central Malawi. Kamuzu Central Hospital (KCH) NRU is situated in Lilongwe, the capital city of Malawi, and is a 1,000-bed referral hospital for Malawi’s central region. The other two NRUs are situated in rural areas: one at St Gabriel’s mission hospital, with 200 beds, and the other at Mitundu community hospital, with 100 beds. The qualitative portion of this study was only carried out at KCH and St. Gabriel’s. All other data were collected at all three NRUs. The study was carried out from May 2005 to January 2007.

There was some consideration of conducting this study in an ACFIN-run nutritional rehabilitation centre, where all of the staffing including physicians and 24 hour nursing care was supplied by expatriate ACFIN staff. Whilst lower levels of mortality have been observed in this type of centre, than in a nutritional rehabilitation programme integrated into the MOH system, it was felt by the study design team that working with the MOH would create results that could be generalised across Malawi and the region.

2.3 Research team roles
The nutritionist research manager (Pamela Fergusson) was responsible for writing the study proposal and protocols, obtaining funding for the research, hiring and overseeing the management of staff, designing the data collection forms, reporting to the MOH Malawi and to the donors, data analysis and research results dissemination through reports, conference abstracts and papers.

Senior research advisors included Professor Andrew Tomkins at the Institute of Child Health, University College London. Professor Tomkins sits on the research advisory
board for ACFIN, and was involved in advising on study design, and research results dissemination through contributions conference abstracts and papers. Professor Tomkins also acted as an external advisor for Pamela Fergusson’s PhD. Professor Sarah Andrew and Dr. Ian McDowell both acted as internal advisors for Pamela Fergusson’s PhD.

The Ministry of Health Nutrition Team, including Teresa Banda and Catherine Mkangama were instrumental in designing the study as well as contributing to conference abstracts and papers.

The research coordinator and the nursing coordinator in Malawi were responsible for the day to day overseeing of staff and performing quality checks to ensure that study protocols were followed. The research coordinator also contributed to the writing of research reports, conference abstracts and papers.

The research nurses were responsible for working alongside the MOH and CHAM nursing staff to provide nursing care in the NRUs, for implementing the study protocols and for completing the data entry forms. The data entry team were responsible for double entry of data, using Epi Info. The nursing and research coordinators, along with the research nurses and the data entry team were employees of AAH Malawi while the qualitative field researchers were employees of REACH Trust, an external organisation.

During 2004, in the planning stages of the research, the research manager visited Malawi to select the research sites. The sites were selected based on the following criteria: within a 45 minute drive of Lilongwe to facilitate transport of whole blood to the lab for CD4 and HIV testing; kitchen facilities for heating water to prepare F75 and F100, sufficient admission numbers to meet sample size requirements, and an interest and willingness at facility level to work with the research team. Three sites were selected.
2.4 Methods
The impact of HIV on mortality and recovery in children with SAM were evaluated using a prospective cohort study. Cohort methods were selected because longitudinal data are necessary to evaluate outcome of nutritional recovery, including mortality and recovery. It was not ethical to design a randomised controlled trial in this case, as HIV status cannot be randomised. The mode of treatment (community vs. facility-based) and/or the type of therapeutic feed could have been randomised; however this would have been an additional variable which could confound the effect of HIV. A case control study might have also been possible; however the predicted sample size was large enough to do a cohort study.

Maternal data were only collected once, on admission to the study, so maternal HIV and nutritional status is reported using cross-sectional methods. Although cross sectional data are limited to a snapshot of reality, it is unlikely that the mothers and other carers of children with SAM would experience significant changes in nutritional or HIV status during the short time period of five months. For this reason it was deemed unnecessary to subject mothers and other carers to multiple data collection episodes.

Maternal and staff perceptions of quality of care were investigated using the grounded theory approach. Grounded theory was chosen as appropriate as there is little published regarding quality of care in inpatient nutritional rehabilitation, and theory could be built from emerging data (Glaser, 1998). Also, qualitative field researchers had the opportunity to spend an extended time in the NRUs collecting data, developing a deep understanding of the context.

2.5 Participant recruitment
All children aged between six and 59 months with a weight for height (W/H) index of less than 70 per cent or the presence of bilateral pitting oedema or a mid upper arm circumference of < 11 cm and their carers were eligible for study recruitment (WHO, 2003). Written consent to join the study and to test both the child and herself for HIV was obtained from all mothers and other carers who agreed to allow their children to
join the study (95 per cent of accompanying carers were mothers). Testing usually occurred within the first three days of admission to the NRU.

Maximum variation purposive sampling (Patton, 1990) was deployed to ensure inclusion of different voices and perspectives: male and female and younger and older carers and those that had been in the NRU for shorter and longer periods were all interviewed. The sampling frame for staff included women and men from different cadres ranging from cleaners to nurses and doctors. As is the norm in qualitative studies, sample size was not predetermined, but rather sampling continued until reaching saturation point (Byrne, 2001; Patton, 1990; Sandelowski, 1995).

Participants were recruited directly by the qualitative researchers within the NRU. Informed consent was negotiated with all participants and confidentiality maintained through the process of data collation, analysis and presentation. Carers and staff were purposively sampled from KCH and St Gabriel’s Hospitals. Inclusion criteria were: being a staff member working within the NRU or accompanying a child to the NRU. Carers remained in the NRU until the child reached nutritional recovery (defined as >85 per cent weight for height and no oedema for ten days), usually for about three weeks.

In this study of caregiver perspectives on the quality of care in the treatment of severe acute malnutrition in children, the term caregivers refers to both hospital staff and also mothers and other carers. Hospital staff caregivers will be specified by their job title. (Chinkhumba, Tomkins, Banda, Mkangama, & Fergusson, 2008).

2.6 Standard care procedures
2.6.1 Nutritional rehabilitation

All children with SAM presenting at the centres underwent nutrition rehabilitation using Formula 75 (F75) and Formula 100 (F100) (starter and catch up formulae specially developed for the nutritional needs of children with SAM) according to national guidelines (MOH Malawi, 2003; WHO, 2003b). Written consent for an HIV test for the child was obtained from all guardians (95 per cent of guardians were mothers) who consented to have their children join the study. Testing usually occurred within the first three days of admission to the NRU. All children and carers for whom consent to join the study was obtained had blood collected for HIV, CD4,
Hb. All children received an equal standard of care, regardless of their guardian’s consent or refusal to join the study.

Nutrition rehabilitation of the children was in accordance with Government of Malawi Ministry of Health’s Guidelines for the Management of Severe Acute Malnutrition (MOH Malawi, 2003), which were adapted from the WHO Guidelines for the Inpatient Treatment of Severely Malnourished Children (WHO, 2003b). Children were recruited at the outpatient department, and those who were severely malnourished were referred for nutritional rehabilitation (WHO, 1999). A small proportion of children with SAM had serious medical complications and were referred directly to the paediatric ward for medical and nutritional care, and not recruited into the study. Children who were admitted to the NRU, but subsequently developed serious medical complications were referred to the paediatric ward.

Nutritional rehabilitation was carried out in three phases (WHO, 1999). Children were weighed on admission and daily during phase one and the transitional phase, then on alternate days during phase two using a paediatric Salter scale with an accuracy of 100g. Height measurements were taken on admission and discharge from the NRU using a paediatric height board with an accuracy of 1mm. Weight change in oedematous children was measured from lowest weight to discharge weight and in marasmic children from admission weight to discharge weight. Skin-fold thickness measurements were taken at two sites as a proxy for body fat. Sub-scapular and triceps skin-fold thickness were measured using a Holtain Tanner/Whitehouse Calliper on admission and repeated on discharge from the NRU, with an accuracy of 1mm. Three readings for each skin-fold measurement were taken each time and the mean of the three readings was used for calculations.

Children were discharged from the NRU back into the community upon reaching nutritional recovery at a target weight for height index of 85 per cent. Their nutrition rehabilitation and monitoring continued at the supplementary feeding clinics (SFC) for four months where they were seen every fortnight to receive food rations (five kg corn soya blend mixed with 500 ml of cooking oil) together with routine nutritional and medical assessment. Mortality was assessed by following children for four months post-discharge from the NRU, or death (if earlier). Children were visited at
home for follow-up if they did not attend the SFC. Urban and rural households were defined by local community-based health staff using addresses, maps and local knowledge.

Cotrimoxazole was prescribed in Malawi during this period for prophylaxis and to treat known HIV-exposed and infected children, although there were some interruptions in supply. These interruptions in supply are an important confounding variable. Paediatric ART was not available in Malawi when the study commenced, and none of the children were on ART upon study admission. All mothers were offered voluntary counselling and testing (VCT); however, entry into the study required them to accept an anonymous, linked HIV test for themselves and their child. In May 2006, with the advent of paediatric ART availability, the study testing protocol was changed to require new study participants to accept HIV testing. HIV-infected mothers and children were referred for HIV treatment and care under MOH guidelines. Twelve HIV-infected children were recruited after this change in guidelines. None of these children were on ART upon NRU discharge. It is unknown how many of these children were initiated on ART under MOH care after discharge from the NRU. Carers who gave consent had their weight and height measured within three days of study entry.

2.6.2 HIV
Paediatric ART was not available in Malawi when the study commenced. All mothers were offered voluntary counselling and testing (VCT); however, entry into the study required them to accept an anonymous, linked HIV test for themselves and their child. In May of 2006, with the advent of paediatric ART availability, the study testing protocol was changed to require new study participants to accept HIV testing. HIV-infected mothers and children were referred for HIV treatment and care under MOH guidelines. All children were treated for SAM regardless of the uptake of VCT by their guardians.

All children were treated for SAM regardless of the uptake of VCT by their guardians. HIV was diagnosed in children >18 months and their carers using two rapid tests: Abbott Determine HIV 1 and 2, and Trinity UNIGOLD HIV 1 Rapid. ‘Positive’ and ‘Negative’ results were those with concordant results for both tests. Discordant
results were confirmed using a Bio-Rad Western Blot. HIV diagnosis for children <18 months was carried out once using PCR, using Roche Amplicor HIV-1 DNA assay (version 1.5). CD4 count (expressed as a percentage of total lymphocytes) was measured using a Beckman Coulter EPICS II machine. HIV and CD4 testing was carried out by the University of North Carolina Laboratories in Lilongwe, Malawi (Fiscus, et al., 2007).

2.7 Measurement tools and indices

2.7.1 BMI

Body mass index (BMI) was calculated using the formula: BMI = weight in kg/height in m². BMI is a widely used anthropometric assessment measure in assessing adult nutritional status. The WHO recommends the use of BMI to classify adults into groups including obese (>30 kg/m²), overweight (>25 kg/m²) normal range (18.5 – 24.99) and underweight (<18.5) WHO further divides underweight into severe thinness (<16.00 <16.00), moderate thinness (16.00 - 16.99 16.00 - 16.99), and mild thinness (17.00 - 18.49) (WHO, 1995).

While BMI is recognised as being one indicator of underweight, it is not always a reliable indicator. When dealing, for example, with individuals who are very tall, or individuals who are very muscular BMI can be deceiving. With individuals who are very tall, practitioners using BMI may be likely to diagnose underweight in individuals who have a normal body weight for their culture and are not at increased risk of underweight-related morbidity. In muscular people BMI may be more likely to indicate overweight, as lean body mass tissue is dense and heavier that fat tissue (WHO, 1995). The Cormic index can be used to help to correct for variability in body shape, in particular the ratio of leg-length to trunk–length (Collins, Duffield, & Myatt, 2000; Norgan, 1994). In this study, however, sitting height was not recorded, and therefore the Cormic index was not calculated. A literature search produced no standard values for Cormic index in Malawian women of child bearing age. A special supplement of the European Journal of Clinical Nutrition, entitled The Functional Significance of Low Body Mass Index reported that “The mean SH/S for European and Indo-Mediterranean populations is about 0.52. Africans have proportionally longer legs, in general, with ratios around 0.51”. One study reporting on Cormic
index in Zimbabwean girls reported a Cormic index of 0.50 at 13 years of age (Olivieri, Semproli, Pettener, & Toselli, 2008).

When conducting a nutritional assessment of an individual, using only one measure is not sufficient to diagnose underweight or overweight. Additional measures including weight history, waist to hip ratio, and body composition analysis can help to form a more complete picture of nutritional risk. In this case, however, individual nutritional assessment of the mothers was not part of the research protocol, and these additional measures may have been seen as invasive. BMI was selected as a measure because it is widely comparable to other population data and it is useful in gaining a picture of the nutritional risk across the whole study sample, rather than individuals. Mid upper arm circumference (MUAC) data were also available for comparison, to create a more complete nutritional picture among mothers and other carers.

2.7.2 MUAC
MUAC is the circumference of the left upper arm, measured at the mid-point between the tip of the shoulder and the tip of the elbow (olecranon process and the acromion) using a flexible tape (Collins, et al., 2000). MUAC is an important measure of nutritional risk in children with SAM as in some studies MUAC alone or MUAC for age has predicted mortality better than any other anthropometric measure (Collins, et al., 2000). MUAC has practical advantages in a research setting, as it is a non-invasive measure which requires minimal equipment. As children’s arms are very small the relative importance of even 1mm of difference makes MUAC reliability vulnerable to measurement error (Collins, et al., 2000). In this study, however, few children were admitted using the MUAC criteria, as most children were oedematous. MUAC is also a useful indicator of nutritional risk in adults (Collins, et al., 2000; PAHO, 1991) in particular to act as a cross check for BMI findings.

2.7.3 Weight for height
Weight for height was used as an admission criterion for this study. Centre for Disease Control’s National Centre for Health Statistics (NCHS) growth standards were used in this study, as the data collection began before the release of the new 2006 WHO growth standards. The NCHS standards were based on the growth of
American, mostly formula fed babies. Using WHO standards would have meant that more children were identified as having SAM, but mortality may have been lower as the malnutrition in these children would have not been as severe (Isanaka, et al., 2009).

Weight for height is prone to measurement error. Height or length can be particularly difficult to measure, as children are often crying and moving. When measuring weight children were suspended on the scale wrapped in a chitenge (fabric used as a wrap). This was a familiar environment and helped children to relax so that more accurate weight measurement could be taken.

The Prudhon index was developed as a method of estimating death rates in children with SAM. The model was developed using data from 2,753 children at eighteen NRUs in Africa (Prudhon et al., 1997). Prudhon Index, \( P \) (deaths) = 
\[
1/(1 + \exp[-(20.63 - 9.99 \ln (\text{weight (kg)} / \text{height (m)} 1.74) + 1.36 \times \text{oedema}])
\]

2.8 Qualitative research techniques
Ethical clearance was granted for the qualitative research by the Malawian National Health Science Research Committee. Sixteen carers (fourteen female and two male) and fourteen members of staff (twelve female and two male) were interviewed between October 2005 and March 2006. The sixteen carers also participated in one of three focus groups. The research was conducted using both male and female Malawian researchers with experience in using different qualitative research methods (interviews, focus group discussions and observation) to explore sensitive topics such as HIV in the Malawi context. The researchers remained within the NRUs conducting observations, interviews and focus groups for six months. Trustworthiness was also enhanced through the researchers’ prolonged engagement with the study setting and participants.

The research design was exploratory; this was particularly important, as prior qualitative research in this area was lacking and the subject was both contextually and culturally bound (Barnett, Miller-Perrin, & Perrin, 1997). The use of qualitative methods allowed researchers to explore the attitudes of different groups; in particular, the unheard voices of mothers and other carers (Aubel, 1991; Eng, 1990;
The study methodology was founded in grounded theory principles (Glaser, 1998). Multiple methods were used to collect data, including interviews, focus groups and observation. This allowed for triangulation of the data. The information was then cross-referenced between staff and carer reports. The team of researchers employed constant comparison between data and emerging theory by regularly reviewing the transcripts and observation records to develop and tailor the question guides to capture all emerging themes. This integration between analysis and data collection is an important feature of grounded theory research (Glaser, 1968, 1998).

In-depth interviews were conducted to explore lived experiences, beliefs, perceptions, and motivations or values (Britten, 1995). These were complemented by focus group discussions to obtain information about attitudes and behaviours sparked through interaction (Kitzinger, 1995) and cross-checked through observation. Focus groups were used with mothers and other carers, but were avoided with staff. This was to avoid the effect of hierarchical relationships between staff members limiting contributions, especially from younger members of staff. Although there were some concerns about using focus groups with mothers and other carers, because of the lack of confidentiality, in the literature some argue that focus groups facilitate discussion allowing less inhibited group members to take the lead in discussion, opening it up for others. Some participants can find participation in a focus group empowering (Krueger & Casey, 2000). Conversely, some participants will fear the lack of confidentiality in the FGD, particularly with sensitive topics like HIV, and this may prohibit disclosure (Kitzinger, 1995).

2.9 Critical appraisal
Critical appraisal and discussion of each section’s work (3.3 – 3.6) was guided by the appropriate Critical Appraisal Skills Programme (CASP) tool. The CASP tools, developed by the NHS Public Health Resource Unit are available at http://www.phru.nhs.uk/Pages/PHD/resources.htm. Each tool is a set of questions designed to match a specific method. The cohort tool was used here for the mortality and nutritional recovery sections (3.3 & 3.4), and modified for use with the maternal nutrition and HIV status section (3.5), which used cross-sectional methods. The
qualitative CASP tool was used in the final results section, the caregivers’ perspectives on quality of care section (3.6).

2.10 Statistical analysis
All data were doubly entered in Malawi, and checked for consistency using range and consistency checks. Data were analysed using Epi Info and SPSS. Statistical analysis was carried out in accordance with the principles in Essentials of Medical Statistics (Kirkwood, Sterne, & Kirkwood, 2003). Ethical approval for the research was given by the National Health Sciences Research Committee of Malawi.

2.10.1 Use of means and medians
Normal distributions for all data were plotted, and skewness (Bowers, 2008) and the Kolmogorov-Smirnov Z statistic (Peat & Barton, 2005) were reported to assess data normality. Non-parametric statistics were used in response to non-normally distributed data (Kirkwood, et al., 2003).

Comparisons between proportions were made using Chi Square, which is a non-parametric statistic appropriate for both normally or non-normally distributed data. Comparisons between medians were assessed using the non-parametric Mann Whitney U test (Kirkwood, et al., 2003)

2.10.2 Use of relative risk
Relative risk is the ratio of an event occurring in an exposed vs. a non-exposed group (Kirkwood, et al., 2003).

RR = probability exposed/probability non-exposed.

For example relative risk was used in this research to quantify the increased risk of mortality in children with HIV infection to those without HIV infection.

2.10.3 Use of sensitivity and specificity
Sensitivity measures the proportion of actual positives which are correctly identified as such and specificity measures the proportion of negatives which are correctly identified (Kirkwood, et al., 2003). For example, sensitivity and specificity was calculated in this research to determine if BMI was a good proxy indicator of HIV status in mothers and other carers of children with SAM.
2.10.4 Use of receiver operating characteristic (ROC) curves

A ROC curve plots the positive rate (sensitivity) against the false positive rate. ROC curves provide a continuous and visual representation of the sensitivity and specificity of a screening test (see figure 14). An ideal indicator has a sensitivity of 100% and a false positive rate of 0%. This type of curve produces the (0,1) point, also called the perfect classification. A random result would produce a diagonal line, passing through the origin and continuing outward with a slope of 1. This is also called the line of no discrimination.

![ROC Curve](image)

**Figure 14: ROC curve**  
Source: (Kirkwood, et al., 2003)

2.10.5 Use of Kaplan Meier

Kaplan Meier is a survival plot indicating how long after an event patients survive. In this study Kaplan Meier was used to compare survival among HIV-infected vs. HIV-uninfected children with SAM. Kaplan Meier is a useful, visual representation of survival over time.
2.10.6 Use of regression analysis

In regression analysis, a binary dependant variable is modelled as a function of the independent or explanatory variables (Kirkwood, et al., 2003). For example, in this research mortality as a dependant variable (died/survived) was modelled against independent variables (presence of oedema, HIV status etc) to determine significant relationships.

2.10.7 Qualitative analysis

All carer interviews and focus groups were conducted in Chichewa (local language) and then transcribed and translated into English. Staff interviews were conducted either in Chichewa or in English, according to participant preference, and then transcribed. Observations were recorded daily in researcher field journals.

All observations and transcripts were read, and analysed by the entire team in a process. Data were then hand coded using line-by-line analysis (Glaser, 1998). An experienced qualitative researcher, reviewed the coding during the research process, and two independent researchers reviewed and coded the transcripts and generated similar themes. The entire research team met regularly to discuss the coding and emerging themes.

A team approach was used in the analysis, including frequent team meetings to review transcripts and discuss with interviewers to capture any emerging themes. An iterative, framework approach to the analysis was used (Patton, 1990), which is consistent with qualitative methodology, in particular with grounded theory (Glaser, 1998). Data were hand coded. In framework analysis a framework for data analysis is developed using the research questions and emerging data early in the research process. All data are coded, and linked to the themes in the framework. As more data emerges the framework is modified to capture any new emerging themes.

2.11 Quality assurance

2.11.1 Selection bias

Selection bias has operated in this research, as children were recruited at the facility level rather than the community level. Results cannot be generalised to population level. This work is, however, relevant to facility level care. Although community-
based nutritional rehabilitation is becoming increasingly common in southern Africa to treat children with uncomplicated SAM, children with SAM and complications are treated in hospital. These findings are applicable in the facility setting in sub-Saharan Africa.

Another potential issue in selection bias involves the selection of Lilongwe district as the research location. The sample was selected from within Lilongwe district in order to facilitate easy transport of whole blood samples to the lab in Lilongwe. It is possible that children and families living in Lilongwe district are somehow different from Malawian children in other parts of the country, or indeed other children in other sub-Saharan African countries. While this risk does exist, results of a systematic review and meta-analysis show that the results from this study are similar to those from studies conducted at facility level in other sub-Saharan African countries. Selection bias related to the sample being selected within Lilongwe district has not affected the results.

2.11.2 Training
Training was conducted by the research manager, the research coordinator, the nursing coordinator, and several of the AAH Malawi programme staff including the HIV programme coordinator and the nutrition programme coordinator. Topics included: nutritional rehabilitation, HIV and nutrition, measuring height, weight and skin-folds, completing reports, teamwork and leadership. Training was conducted in March/April 2004, and in-service refresher training was repeated every six months throughout the project.

2.11.3 Reliability checks
Regular data reliability audits were performed by the research coordinator and nursing coordinator on weekly visits. All charts of children in the research study were checked for completeness each week, and the research and nursing coordinators re-took weights and heights from a selection of children to cross check the values recorded in the charts. The skin-fold measurements were each taken three times, all three values were recorded and the mean of the three results was taken as the value used in the results section.
All data were doubly entered in Malawi, on two separate computers by two data entry clerks. These two computers were not networked or connected to the internet to reduce the chance of virus infection. The data entry computers were not used for any tasks except study data entry. At the end of the study, before the final data analysis was conducted, the two complete data bases were transferred from Epi Info to Microsoft Access and compared for any inconsistencies. Less than 1% of fields were discordant and these inconsistencies were resolved by going back to the original paper data entry forms.

2.11.4 Trustworthiness in qualitative data
Data obtained from in depth interviews, was cross checked with data from focus groups and observations. This process of confirming results across different data sources is known as triangulation, and this enhances trustworthiness and increases rigour in qualitative research (Patton, 1990).

Member checking was used to seek verification of emerging themes with research participants and other key stakeholders in the analysis process, to allow them to confirm, modify or refute the major themes derived from the analysis and to provide clarification regarding any aspects of the research which required further exploration (Tobin & Begley, 2004).