National Micronutrient Malnutrition Study

Somalia 2009

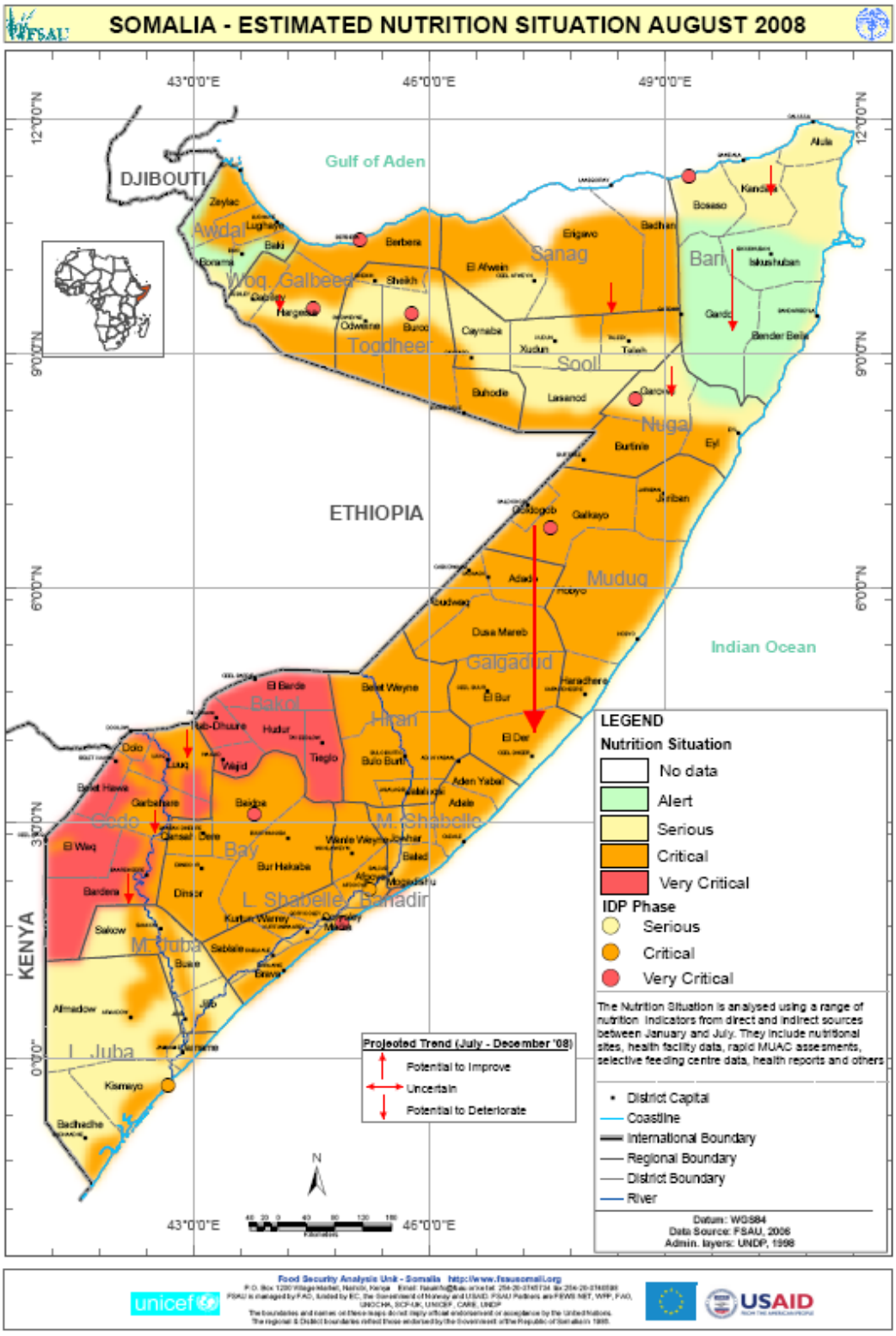
Protocol v19

February 2009

FSAU-FAO and
The UCL Centre for International Health and Development

in collaboration with
UNICEF, CDC, WHO and WFP

Map of Estimated Nutrition Situation in Somalia – August 2008



Context:
Widespread insecurity, lack of infrastructure and low levels of humanitarian access continue to define the environment in Somalia. Health indicators in Somalia remain among the worst in the world. Life expectancy stands at 45 years. One in every seven Somali children dies before the age of five. Approximately 43% of Somalis live below the extreme poverty line. Polio – which re-emerged in Somalia in 2005 after three polio-free years – seems to have been brought under control, with no new cases since March 2007. However, malaria, TB, diarrhoeal diseases and other preventable or easily treated diseases continue to kill thousands each year. Acute respiratory illness is common, especially among children, due to the near universal use of solid fuels for cooking and the lack of adequate household ventilation. Health care facilities are scarce, with an estimated one physician per 25,000 people. More than half of health care staff are unskilled, with little opportunity to receive quality training. Security is the main impediment to accessing health care, as staff are sometimes unable to reach their workplace, or potential beneficiaries are unwilling to take risks in order to reach a health centre which offers inadequate services.

Throughout Southern and Central Somalia, typical levels of acute malnutrition in children below the age of five years, *outside times of crisis*, remain at appallingly high levels, over 15%[1] in most areas. In the north of Somalia, in areas enjoying greater peace, stability and development, malnutrition rates are consistently and substantially lower, median rates over the past 7 year of about 10% in Somaliland with 14% reported in Puntland. Substantial pockets of high vulnerability are also seen in the urban centres, displaced people's camps and areas experiencing extreme environmental degradation. High levels of *severe*[2] malnutrition (up to 5% in some recent assessments); represent the high proportion of children under five that face a high risk of death. A generally high incidence of diarrhoea, the endemic Acute Watery Diarrhoea (AWD) outbreaks and other communicable diseases coupled with low[3] immunisation coverage for measles further increase this risk. Throughout the country, levels of malnutrition are consistently and significantly beyond acceptable levels. To date in 2007, out of 24 nutrition assessments conducted in South and Central Somalia nineteen have reported levels of acute malnutrition above the emergency threshold of 15%. (*see Map*) The causes of the chronic acute nutrition crisis are multi factoral, linked to high rates of morbidity, limited access to safe water and sanitation facilities, which are exacerbated by periods of food insecurity caused by drought floods and conflict, all recurrently experienced by large proportions of the population in South Central Somalia. Rates of chronic malnutrition with median rates for the past 7 years also remain unacceptably high at 25% in South/Central, 21% in Puntland and 16% in Somaliland.

With such a demonstrated nutrition crisis, an understanding of the public health significance of micronutrient malnutrition is essential to explore the potential contributions of these deficiencies to the overall crisis. Unfortunately, in spite of a significant amount of nutrition information available, there is a complete lack of representative data available on micronutrient deficiencies both regionally and nationally. Until this information is available a detailed understanding of the actual underlying causes and an appropriate response to tackle this crisis will not be possible.

[1] Global Acute Malnutrition. Below -2 SD from median weight for height of reference population.
[2] Severe malnutrition; below -3 SD from median weight for height of NCHS 1978 reference population.
[3] Average vaccination coverage for measles in the 13 assessments performed in 2007 was 38%

Study Justification:
Somalia is facing a chronic nutrition crisis with rates of acute and chronic malnutrition consistently exceeding emergency thresholds in some areas for over 10 years. Research into the underlying causes has identified high rates of morbidity as the major driving force behind these persistently high rates of malnutrition. The situation is facilitated by low immunization coverage and exacerbated by periods of food shortage, and limited basic social services. Anecdotal evidence has identified cases of Vitamin A deficiency and Iodine deficiency at community level however the availability of prevalence data to determine the public health significance of the main micronutrient deficiencies disorders in Somalia is sadly lacking.

The only available information on anaemia in children 6-59 months is from Somaliland in 2001, where a study conducted UNICEF and the MoH identified 59.5% of children as anaemic, from a sample of 784 children drawn from 30 clusters and tested using a HemoCue: 18.3% mild anaemia, 33.2% moderate anaemia and 8% severe anaemia.

In the MICS 2006, UNICEF identified that only 1.2% of households were using iodised salt nationally, and there was only 24% coverage of Vitamin A capsule distribution in children under five years. This information, though limited, highlights the extreme risks to Vitamin A, Iodine and Iron deficiency in Somalia.

Therefore, a study to determine the public health significance of micronutrient malnutrition in Somalia would provide the detailed information with which to improve understanding of overall nutritional vulnerability. This, in turn, will contribute to developing a more appropriate and evidence based response strategy to tackle the causes and management of the current nutrition crisis.

Study Purpose:
The purposes of this study are twofold:

1. Determine the public health significance of Vitamin A, Iron and Iodine deficiencies in the Somali population to inform and advocate for appropriate responses.
2. Determine a baseline of the levels of deficiencies of the major micronutrients in Somalia for monitoring response

Study Objectives:
Due to the prevailing high levels of insecurity the study objectives have been classified as Essential (E) and Desirable (D). Assuming the current levels of insecurity persist, only the essential objectives will be considered. However, if an improvement in the security situation occurs, Desirable objectives will be considered for inclusion. The final decision will be made following the pilot testing of the survey tools.

- To determine the prevalence of Iron deficiency and anaemia in children 6-59 months and women of reproductive age using biological indicators (E)
- To determine the prevalence of Vitamin A deficiency in children 6-59 months and women of reproductive age using biochemical indicators (E)
- To determine the prevalence of iodine deficiency in school aged children using biological indicators (E)
- To determine the prevalence of iodine deficiency among women (15-49) (E)

- To assess the anthropometric status of children 0-59 months and women of child bearing age. (E)
- To assess the immunization status of children for Measles, Vitamin A, Polio, DPT3 and the status of maternal tetanus coverage (D)
- To determine the prevalence of malaria, *Plasmodium falciparum* using rapid diagnostic tests in household members (all ages) (D)
- To determine the coverage of Insecticide Treated bed Nets (ITN) (E)
- To assess the proportion of households using iodised salt (E)
- To assess infant and young child feeding practices (D but E for exclusive breastfeeding according to international tools)
- To assess the diversity and frequency of consumption of locally available micronutrient rich foods though dietary diversity assessment on children and mothers. (E)
- To determine the knowledge behaviours and practices related to the consumption of iodised salt and micronutrient rich locally available foods. (D)

Target Population:
The target population for this survey will be resident and internally displaced people within the three zones of Somalia. Resident or displaced status will be taken into account during analysis and results presented with cross-tabulations where appropriate. Data will also be collected on the time since displacement.

Study Design:
The study will be a national cross sectional survey with the three zones of Somalia treated as separate strata, allowing estimates at both zone and national level. Due to lack of reliable population list data a two-stage cluster sampling design is proposed. Probability proportional to size will be used for the first stage of sampling at regional level and second level sampling will use a combination of mapping, segmentation, population lists, or modified EPI sampling depending on the areas being surveyed. Thirty-five clusters will be sampled in each stratum, giving a total of 105 in the whole of Somalia.

Utilising a standard cluster survey design subjects will be sequentially sampled in each cluster to yield the desired sample size for each population group and parameter.

Sample Size:
The sample size required for each survey zone (strata) is based on the assumed prevalence given below and the desired precision for each parameter. The calculation of sample size used a population of 999,000, a confidence interval of 95%, an assumed design effect of 1.0 for infant feeding indicators, 1.5 for micronutrient parameters and 2.0 for other measures, and a non-response of 10%. Calculations were performed using EpiInfo 6.04.

Results of the sample size calculations are given in table 1. This shows the sample size required for measuring different indicators in each population group, e.g. children 6-59 months, each zone, and the 3 zones combined. The population groups which will be sampled for each measure are indicated in table 3. To determine how many people will be sampled in each cluster the sample size is divided in to the number of clusters (35) and rounded up to a whole number. For example, 241 children aged 6-59 months are required for the measurement of retinol binding protein (RBP). This is equivalent to 7 subjects per cluster. As both RBP and sTfR are

derived from DBS the larger sample size (241) will be used for this and the hb analysis.

Table 1: Sample Size Required for Different Indicators

Indicator	Estimated Prevalence (%)	Reference	Required Precision (%)	Sample size		
				Group	Zone	Total
Global Acute Malnutrition[1]	18.7	FSAU survey database	4.0	811	811	2433
Vaccination status[2]	35	MICS (2006)	5.0	777	1554	4662
Exclusive Breastfeeding	13	MICS (2006)	7.0	99	99	297
Anaemia	50	Somaliland anaemia study (2002)	8.5	222	666	1998
Iron deficiency	50	African refugee populations[4]	8.5	222	666	1998
Vitamin A deficiency	40	African refugee populations[5]	8.0	241	723	2169
Iodine deficiency[3]	n/a	n/a	-	300	600	1800

[1]Median estimates of global acute malnutrition for Somalia from data collected over the last 7 years are approximately 16% in South Central, 15% in Puntland and 12% in Somaliland.
[2]For immunization status, prevalence estimates from the UNICEF MICS 2006 study for children under five years approximated 35% for Polio, 12% for DPT and 19% for Measles. Vitamin A capsule distribution coverage was 24%.
[3]Iodine deficiency will be measured by determining the median urinary iodine concentration. A minimum sample of 300 children and women per strata will be sampled.
n/a - not available

Data Collection Tools:
The survey data collection tools will be separated into a number of different modules:

Module 1 will include questions relating to the household
Module 2 will include questions and measures of infant (0-5 months) nutritional status and dietary intake
Module 3 will include questions and measures of nutritional status for children 6-59 months.
Module 4 will include questions on children 6-11 years
Module 5 will include questions and measure on women aged 15 – 49

Variable measurement:

- **Household Characteristics** - Information on general demographics of the household will be collected. This will include family size, gender of head of household, livelihood, and education level of carer.

[4] Seal, A. J., Creeke, P. I., Mirghani, Z., Abdalla, F., McBurney, R. P., Pratt, L. S., Brookes, D., Ruth, L. J., & Marchand, E. (2005) Iron and vitamin A deficiency in long-term African refugees. J.Nutr. 135: 808-813.
[5] Seal, A. J., Creeke, P. I., Mirghani, Z., Abdalla, F., McBurney, R. P., Pratt, L. S., Brookes, D., Ruth, L. J., & Marchand, E. (2005) Iron and vitamin A deficiency in long-term African refugees. J.Nutr. 135: 808-813.

- **Anthropometry –** Weight, height, and MUAC data will be collected using standard methods. Sitting height will be measured and standing height/sitting height ratios will be determined for adult women to allow for adjustment of BMI measurements using the Cormic Index.[6]

- **Vaccination status –** Vaccination will be assessed by questionnaire and the examination of health cards where available. Due to the likely non-availability of health record cards the question will probably focus on just the measles antigen.

- **Vitamin A capsule coverage –** Receipt of an appropriate high dose vitamin A capsule will be assessed by questionnaire and showing of an example of a capsule to the carer of children aged 6-59 months.

- **Biochemical Indicators for Iodine, Vitamin A and Iron Deficiency Anaemia –** Peripheral blood will be collected from a finger tip lancet incision. Fresh blood will be tested to determine the concentration of haemoglobin. Dried Blood Spots will be used to store and transport whole blood samples for the analysis of indicators of Iron and Vitamin A status. A sub sample (approx 10%) of capillary blood samples will be collected for calibration purposes. Urine samples will be collected for analysis of iodine status.

Table 2: Biochemical Indicators for Micronutrient Malnutrition

Nutrient	Indicator to assess	Sample
Anaemia	Haemoglobin	Fresh peripheral blood
Iron status	Serum Transferrin Receptor (sTfR)	Dried peripheral blood spot
Vitamin A status	Retinol Binding Protein (RBP)	Dried peripheral blood spot
Iodine status	Urinary Iodine	Urine
Acute phase response[1]	CRP	Dried peripheral blood spot

[1]Measurement of acute phase indicators allows for adjustment of serum nutrient levels to allow for infection

Blood collection and measurement of haemoglobin - Peripheral blood samples will be collected from a finger prick made using a safety lancet (HemoCue® AB). One drop will taken for Hb measurement and further samples from the same finger stick taken for biochemical and parasitological analysis. Anaemia will be assessed using the HemoCue B-haemoglobin Photometer, utilizing the azide methemoglobin principle. Cut-off values for defining anaemia will be taken from WHO recommendations.

Measurement of sTfR, RBP and CRP - Samples collected and stored as Dried Blood Spots (DBS) will be analysed by Dr. Juergen Erhardt at the University of Indonesia in Jakarta. For the measurement of sTfR, RBP and CRP

[6] Adults, Assessment of Nutritional Status in Emergency-Affected Populations (2000) Collins S, Duffield A, Myatt M. ACC/SCN, Geneva
http://www.unsystem.org/SCN/Publications/RNIS/adultrnissupplement.pdf (accessed 25.06.08)

the proteins will be extracted in phosphate buffered saline overnight from a 3 mm punch. After extraction, a standard Sandwich ELISA procedure will be used to measure the proteins in the appropriately diluted extracts.[7] For calibrating the results obtained from DBS the measured values will be compared with results obtained from analysis of paired serum samples. This paired analysis will be performed with approximately 10% of the total sample size. Results from DBS and serum analysis will be plotted on a scatter plot and a regression equation calculated using DBS as the dependent variable. This equation will then be used to adjust the values from the DBS analysis.

For assessing overall assay accuracy and precision serum samples from a quality assurance program of the CDC in Atlanta will be used.[8]

Analysis of urinary iodine - Urine samples will be analysed at the Department of Clinical Chemistry, Saint-Pierre Hospital, Brussels, Belgium. Analysis will be performed on a fully automated Technicon Autoanalyser II. After strong acid digestion of the urine samples, the Sandell–Kolthoff reaction, catalysed by iodine, results in the reduction of ceric ammonium sulphate (yellow) to the colourless cerous form in the presence of arsenious acid.[9]

- **Malaria –** Rapid diagnostic Tests will be used to asses the prevalence of *Plasmodium* Falciparum.

- **Individual Food Frequency and Dietary Diversity Score -** Information on infant and child feeding will be collected using a 24 hour recall food frequency questionnaire. Items for inclusion on the questionnaire will be decided based on key informant interviews and focus group discussions. Individual diet diversity scores will be calculated based on current recommendations.[10]

- **Availability of iodised salt -** Household salt samples will be tested for iodization using a portable spot test kit. A sub-sample of salt will be collected for later quantitative laboratory analysis by titration.

Proposed Coordination and Staffing Structure:

Nairobi:

- **Overall Coordination**

  - FSAU will have overall responsibility for project management of the survey activities. CIHD will work closely with FSAU in Nairobi during the planning,

[7] J.G. Erhardt, J.E. Estes, C.M. Pfeiffer, H.K. Biesalski, N.E. Craft (2004) Combined measurement of ferritin, soluble transferrin receptor (sTfR), retinol binding protein (RBP) and c-reactive protein (CRP) by an inexpensive, sensitive and simple sandwich ELISA technique. J Nutr. 2004 Nov;134(11):3127-32.
[8] http://www.cdc.gov/labstandards/vitaleqa.htm
[9] Riley M, Gochman N. A fully automated method for the determination of serum protein-bound iodine. Presented at Technicon Symposium, Tarrytown, NY, 1964.
[10] http://www.fantaproject.org/index.shtml

implementation and analysis of the survey data. FSAU consultants will lead and undertake the field work inside of Somalia.

- CIHD will provide training and technical support for survey implementation with staff based and resident in Nairobi. CIHD will also be responsible for sub-contracting laboratory analysis of survey samples, data collation and, together with UNICEF, the quality control of data entry. As detailed in the Letter of Understanding with FAO, CIHD will:

  (i) Provide technical support and assistance to FSAU for designing, planning, and conducting the survey activities
  (ii) Conduct analysis of biochemical specimens collected during the survey
  (iii) Analyse the collected data
  (iv) Prepare a project report documenting the conduct and findings of the survey
  (v) In collaboration with FAO and other partners, prepare technical papers based on the survey findings for publication in peer-reviewed journals

Somalia:

- **Sub Regional Coordinators and Supervisor** - FSAU has a team of 13 experienced nutrition field analysts based at regional level in Somalia. These staff would be fully dedicated to the MDD study and will serve as supervisors and logistic coordinators at sub regional level. Further coordinators may be provided by UNICEF/ WHO / WFP (TBC). In addition, efforts will be made to ensure dedicated staff from the regional MoH for the full duration of the study as coordinators

- **Team Leaders -** Team leaders will be requested from the operational health UN and NGO agencies at sub regional level or recruited locally.

- **Nurses** – following the inclusion of RDT to estimate malaria prevalence in FSAU nutrition surveys, nurses are being employed for every survey, these same staff may be identified for the MDD study. Efforts to recruit where possible from MoH and NGO staff would be made.

- **Enumerators -** will be identified on the basis of their experience in conducting assessments. Given the regular nutrition assessments conducted by FSAU availability of experienced enumerators at sub regional level is possible. Efforts to recruit where possible from MoH staff will be made.

Logistic Support:

Within Somalia main towns have been identified in all three regions which will serve as logistic bases.

- South Central Somalia: Baidoa, Wajid, Jowhar and Belet Weyne. (Mogadishu excluded due to current conflict which is unlikely to be resolved in the coming months)
- Puntland: Bossasso, Galkayo and Garowe.
- Somaliland: Hargeisa, Burao and Berbera.

In each of these major towns cold chain facilities and basic laboratory facilities are likely to be available. There availability will be confirmed by a preliminary assessment conducted by a FSAU consultant before the main study begins.

UN flights operate six days a week (excludes Friday) into the major towns in Somalia, in addition ECHO operates flights 6 days a week in South Central and Northern parts of the country.

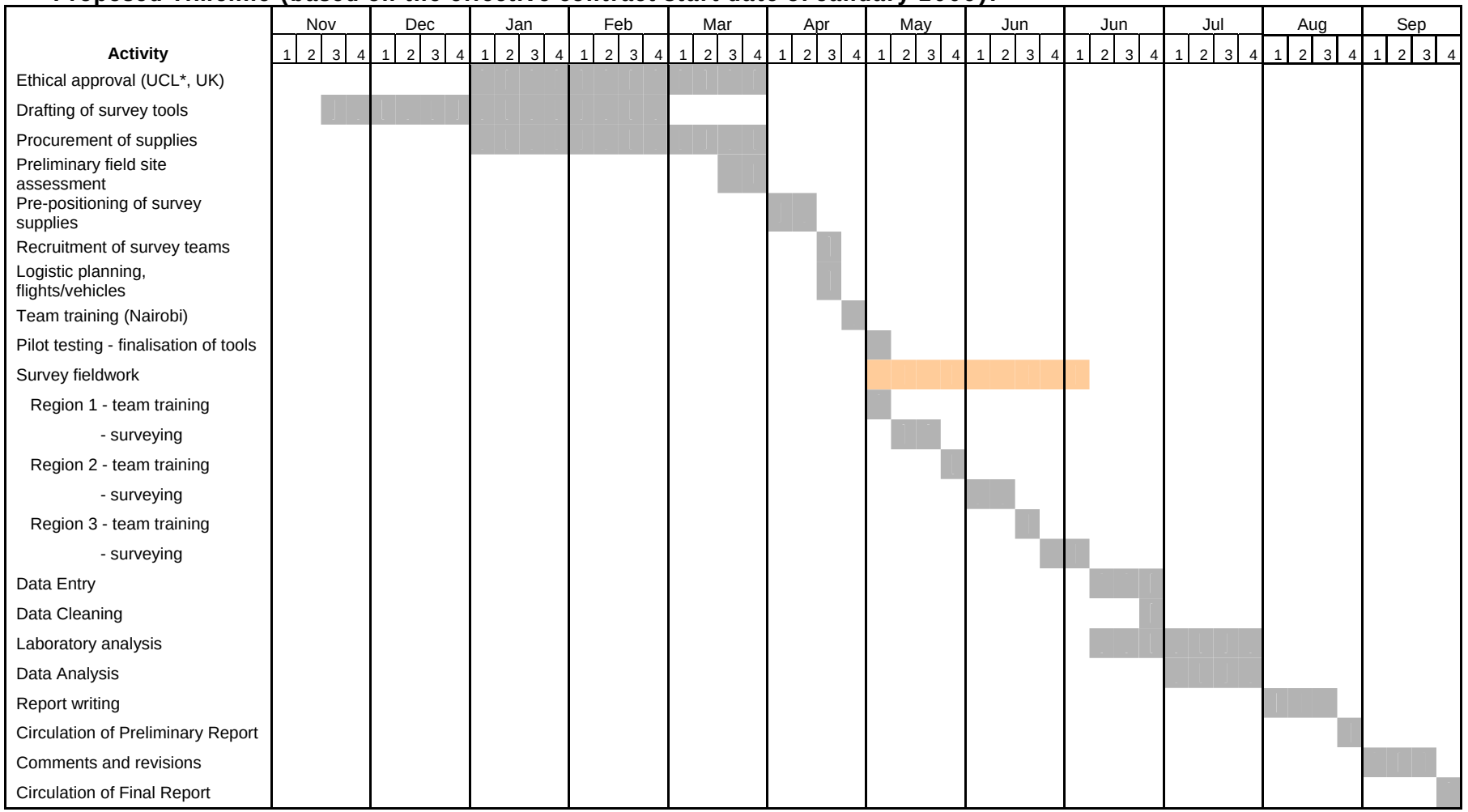
Table 3: Summary of data to be collected for each age group

Age Group	HH Question-naire	Anthro-pometry	Immun-isation Status	FFQ	Infant feeding	Urinary Iodine	Retinol Binding Protein	Haemo-globin	sTfR	APPs	Malaria Prevalence
Infants 0-5 months	√	√		√	√						√
Children 6-23 months	√	√	√	√	√		√	√	√	√	√
Children 24-59 months	√	√		√			√	√	√	√	√
Children 6-11 years	√	√		√		√	√	√	√	√	√
Women 15-49 years	√	√	√ (Maternal Tetanus)	√		√	√	√	√	√	√

Table 4: Procurement and donation of supplies:
It is assumed that the following items will be provided by UNICEF

Analysis of iodised salt	Rapid Test Kits
Malaria testing and treatment	Rapid Diagnostic Tests Treatment for positive cases ACT (anti-malarial drug doses for all ages) assuming 15% prevalence
Anaemia testing and treatment	Haemocue 201+ Haemocue cleaner Haemocue cuvettes (containers of 50) Lancets (boxes of 200) Iron tables+ Folic acid for anaemia treatment (assuming 40% prevalence)

Proposed Timeline (based on the effective contract start date of January 2009):



*University College London

Risks and Assumptions:
Insecurity preventing access is a major constraint particularly in South Central Somalia and more recently in Puntland. Obviously this will have an impact on the study in terms of accessing the identified selected clusters. A sampling plan that allows for the use of replacement clusters will be developed to reduce the risk of insecurity preventing successful completion of the survey. However, failure to complete the survey due to inadequate security conditions remains a real possibility. Seasonal factors may also be important constraints to survey completion. During the rainy season areas in the south become difficult to reach due to poor roads. Migration behaviour of pastoralists may change according to climatic conditions and this may make certain populations harder to access.

Security Situation:
From January 2007 to December 2008, the security situation has deteriorated significantly throughout Somalia which is likely to impact significantly on the fieldwork. The following is a summary.

- Significant increase in attacks between, TFG, Ethiopian and anti governments leading to increased displacement from Mogadishu, Belet Weyne, Juba and Central regions.
- Significant targeted increases in attacks and killings of aid workers.
- Suicide bombings targeted at UNDP office in Hargeisa leading to reclassification of security phase in Somaliland to Phase 4.
- Increasing printing of money caused hyperinflation and increased food prices, causing further stress on HH causing increased displacement and refugees.

The above factors have, therefore, created a very challenging environment for conducting fieldwork and are likely to have the following consequences:

- Limited access for international UN staff to only major urban centres, thereby reducing supervision of field work
- Limited field access for UN national staff thereby increasing reliance on local partners (NGO, SRCS, MoHL...etc)
- Certain areas may not be accessible; this can change on a day by day basis.
- Restriction on flights may impact on staff movement, supplies movement, specimen delivery etc

Mitigation Measures:

- Intensive training of Somali national staff and partners – extra days to be added for pilot testing and standardization tests.
- Back up staff from local partners in the event UN national staff have access
- Extra days for fieldwork considered in budget and plan
- Extra supplies to be prepositioned in central areas in case of logistic challenges
- Enhanced cold chain in the event of delays for flights to deliver specimens to Nairobi

In the event that insecurity completely restricts access to South Central, surveys would only be conducted in Somaliland and Puntland. In the event that insecurity also completely restricts access to one or both of these areas survey work will focus on those regions or areas that are accessible. The final decision on the scope and conduct of the planned field work will be made in the 2 weeks prior to its commencement. The scope of field work

may also be changed subsequent to this decision if security conditions change.

Partner contributions: (complementary to FSAU/FAO and UCL-CIHD)

- **CDC – Atlanta**

The technical expertise of CDC will be consulted during the designing of the survey sampling plan.

- **UNICEF**

With the extensive experience of UNICEF in conducting similar studies, more recently in Afghanistan and Darfur, contribution of experienced staff will be important to ensure the quality of the fieldwork. In addition, as the main procuring agencies for nutrition and MDD survey equipment, support in the form of the necessary equipment will also be essential.

- **WHO**

Similarly to UNICEF, WHO has extensive experience in conducting such studies. Technical inputs into the survey design have already been provided to FSAU and will continue to be sought during the detailed planning phase.

- **WFP**

As for UNICEF and WHO, WFP is also very experienced in conducting nutritional studies, therefore, similar requests for qualified staff to facilitate good quality field work will be sought. Also, given the logistical advantage of WFP, further support to implement field level activities will be key, such as transport of equipment and biological specimens.

Survey Budget

Item	*Number*	*Unit cost ($US)*	*Amount ($US)*
FAO			
Survey coordinator (months)	3	3,000	9,000
Field laboratory coordinator (months)	4	1,500	6,000
Support costs for regional offices:			
North-West			21,098
North-East			21,648
Central			21,648
South			21,648
Staff DSA and Visas			23,800
International flights (Nairobi - Somalia)			75,000
Printing and dissemination			5,000
Contingency (10%)			20,484
Subtotal			***$225,326***
Partners - UCL-CIHD			
Project advisor – Andrew Seal (Pt 44; 10% FTE for 10 months)	10	1,044	10,440
Survey coordinator – Ismail Arte rage Kassim (Pt 26; 100% FTE for 7 months)	7	6,190	43,330
International travel (London - Nairobi)	5	1,800	9,000
Travel insurance and vaccinations	2	300	600
Visas	4	50	200
Subsistence (days)	40	250	10,000
Data analysis			20,000
Training materials	1	500	500
Laboratory analysis (ELISA DBS assays for iron and vitamin A)	1,400	10.00	14,000
Laboratory analysis (Serum assays for validation study)	330	10.00	3,300
Laboratory analysis (Urinary iodine analysis)	1,000	12.00	12,000
Laboratory analysis (salt iodine titration)	100	12.00	1,200
Sample shipping	1	200	200
Administrative support			1,000
Contingency (5%)			3,060
Organisational overhead (15%)			19,324
Subtotal			***$148,154***
Total			**$373,480**