Appendix 7

Question 19: data extraction tables

Shortened data extractions were prepared to obtain information for question 19, 'What methods are effective for treating SAM among infants < 6 months old?'. Only two studies presented information separately for this age group; however, neither study focused on this age group. No quality assessment was undertaken for either study.

Nu Shwe 2003[47]

Data extraction table

Reference and design	Intervention	Participants	Outcome measures
Author: Nu Shwe[47] *Year:* 2003 *Country:* Myanmar (Burma) *Study design:* cohort with historic control *Setting:* secondary care *Number of centres:* one *Funding:* NR	*Intervention:* the WHO guidelines for management of SAM (with two modifications – all assumed to have hypoglycaemia and given 10% sucrose on admission, monitoring of pulse and respiration every 30 minutes instead of every 10 minutes) *Control:* standard management of SAM prior to introduction of the WHO guidelines. No details provided *Other interventions used:* critical-care pathway introduced in late 2001	*Definition of SAM:* W/H or W/L < 70% of the NCHS/WHO reference and/or symmetrical oedema of the feet *Number of participants:* control year 1999 = 157, of which 18 (11.4%) were < 6 months of age; WHO year 2000 = 196, of which 21 (10.7%) were < 6 months of age; WHO year 2001 = 186, of which 12 (6.4%) were < 6 months of age; WHO year 2002 January to August = 117, of which six (7.7%) were < 6 months of age *Sample attrition/dropout:* NR *Sample crossovers:* not applicable *Inclusion criteria:* W/H or W/L < 70% of the NCHS/WHO reference and/or symmetrical oedema of the feet *Exclusion criteria:* NR *General characteristics of participants:* severely malnourished children admitted to Yangon Children's Hospital	*Primary outcomes:* not stated *Outcomes:* outcomes reported include mortality, duration of hospital stay, readmissions, time taken for recovery. The only outcome reported separately for the < 6 months age group was proportional mortality *Method of assessing outcomes:* not stated *Adverse symptoms:* not stated *Length of follow-up:* not stated *Recruitment dates:* January 2000 to August 2002

Characteristics of participants

Characteristic	WHO year 2000 (*n* = 196)	WHO year 2001 (*n* = 186)	Control year 1999 (*n* = 157)
Age mean, months (range)	29 (39 days–12 years)	28 (2 months–12 years)	25 (39 days–11 years)
Children with oedema, *n*	12	12	15
Children with skin lesions, *n* (%)			34 (21.7)

Comments: characteristics are available only for the whole group, they are not available separately for the group of infants aged < 6 months. Only age, number of children with oedema and with skin lesions have been data extracted. Data on children with hypothermia, hypoglycaemia, mean weight and mean length have not been data extracted. Data extracted only for full years (not the partial year 2002)

Results

Primary outcomes	WHO year 2000 ($n=21$)	WHO year 2001 ($n=12$)	Control year 1999 ($n=18$)
Proportional mortality for < 6 month age group (%)	Cases: 10.7 Deaths: 9.1	Cases: 6.5 Deaths: 12.5	Cases: 11.4 Deaths: 12

Comments: only results for the 0–6 month age group have been data extracted as these may inform question 19. The overall results have not been data extracted because they relate to question 1, which was not ranked in the top 10 questions by the Delphi process

The paper states that, comparatively, the proportional mortality in the age groups < 6 months and 6–12 months was lower than in the 13–24 months and > 24 months age groups (9–24% vs 20–50%). The author also comments that overall SAM in children < 6 months of age had significantly reduced due to implementation of exclusive breastfeeding programmes in hospital, clinic and community. The lower proportional mortality observed in the < 12 months age groups may also be due to the impact of breastfeeding

Safety: NR

HIV: NR

Barriers to implementation

Some barriers reported relating to the overall study and implementation of the WHO guidelines, but no barriers specifically relating to children < 6 months of age were reported. Aspects that may have affected this age group include difficulty obtaining ready-made combined mineral–vitamin mix, impracticality of monitoring pulse and respiration every 10 minutes (staff did their best to monitor every 30 minutes) and blood glucose could not be tested in every child, so all children were assumed to have hypoglycaemia and given 10% sucrose solution on admission

Other barriers reported related to the critical-care pathway, but as the details of this are not clear these have not been extracted

Methodological comments

Allocation to treatment groups: not applicable as this was a cohort study with retrospective control

Blinding: not explicitly stated, but presume none

Comparability of treatment groups: comparability of the 0–6 month age group in each trial arm unknown as data not provided. Baseline characteristics of the participants for each year are broadly comparable although with some changes (e.g. number of children under 6 months admitted occurring over time)

Method of data analysis: NR

Sample size/power calculation: NR

Attrition/dropout: NR

General comments

Generalisability: difficult to assess. The numbers of children aged < 6 months were small and there was a lack of data presented separately for them

Outcome measures: only one outcome measure, proportional mortality, reported for the 0–6 month age group

Intercentre variability: not applicable, but there may have been variations between years

Conflict of interest: NR

NR, not reported.

Hossain *et al.* 2009[48]

Data extraction table

Reference and design	Intervention	Participants	Outcome measures
Author: Hossain *et al.*[48] *Year:* 2009 *Country:* Bangladesh *Study design:* prospective cohort with concurrent control *Setting:* secondary care *Number of centres:* two *Funding:* ICMH	*Intervention:* ICMH protocol for management of SAM with no phasing *Control:* WHO protocol with two phases of management of SAM; the ICMH and WHO protocols are outlined separately below *Other interventions used:* none	*Definition of SAM:* W/H < 70% of the expected NCHS/WHO references with or without bilateral pitting oedema *Number of participants:* 60 (number aged < 6 months NR), 30 in each group *Sample attrition/dropout:* reported for whole group only *Sample crossovers:* NR *Inclusion criteria:* SAM children aged 2–59 months with W/H < 70% of the expected (NCHS/WHO references) with or without bilateral pitting oedema *Exclusion criteria:* children with major congenital abnormalities or disabilities and having feeding difficulty *General characteristics of participants:* in addition to having SAM, all belonged to urban and periurban areas of Dhaka	*Primary outcomes:* not explicitly stated but presumed to be weight gain (in gram per kg per day) as the sample size calculation was based on this *Other outcomes:* improved appetite, disappearance of oedema, improvement of other associated medical conditions, time taken for gaining target weight, mortality rate *Method of assessing outcomes:* target weight-W/H reaching 1 SD (90%) of NCHS/WHO median reference values *Adverse symptoms:* NR *Length of follow-up:* not explicitly stated, appears to be to discharge *Recruitment dates:* June to December 2003

Characteristics of participants

Characteristic	ICMH intervention ($n=30$)	WHO control ($n=30$)	*p*-value
Age (months), mean ± SD	17.90 ± 14.17	18.33 ± 13.76	0.90
Sex ratio, F : M	1 : 1	1 : 1	
Nutritional status			
Marasmus, *n* (%)	20 (66.8)	20 (66.8)	NR
Marasmic kwashiorkor, *n* (%)	5 (16.7)	4 (13.3)	0.9
Kwashiorkor, *n* (%)	5 (16.7)	6 (20)	NR

Comments: characteristics are only available for the whole group, they are not available for the group of infants aged < 6 months. Only age, sex ratio and nutritional status have been data extracted. Data on parents' education, profession and income has not been data extracted

Results

Primary outcomes	ICMH intervention	WHO control	*p*-value
Weight gain for 0–6 month age group, mean ± SD g/kg/day	17.5 ± 7.5 (*n* unknown)	11.6 ± 6.8 (*n* unknown)	0.21

Comments: only results for the 0–6 month age group have been data extracted as these may inform question 19. The overall results have not been data extracted because they relate to question 1, which was not ranked in the top 10 questions by the Delphi process

Safety: NR for 0–6 month age group

HIV: NR

Barriers to implementation

Copper not available in the local market, so this could not be used in the provision of minerals and trace elements

Methodological comments

Allocation to treatment groups: children at one hospital were managed with the WHO protocol, children at the other hospital were managed with the ICMH protocol. No information regarding allocation of each hospital to which protocol

Blinding: not stated

Comparability of treatment groups: comparability of the 0–6 month age group in each trial arm unknown as data not provided. Baseline characteristics of the complete trial arms are comparable

Method of data analysis: data for appetite, weight, oedema and other clinical parameters were collected daily through a structured questionnaire and checked manually at collection period and prior to entry into Microsoft Access (Microsoft Corporation, Redmond, WA, USA) and subsequently SPSS/PC+ for analysis. Student's *t*-test was used for comparing continuous variables and the chi-squared test was used for comparing the mortality rate

Sample size/power calculation: a sample size for equivalence was calculated assuming that the mean time taken for targeted weight gain is 25 days in each group with a SD of 6 days. Minimum acceptable difference in the two groups was set at 4.5 days with alpha error of 0.05 and power 80%. Study unlikely to be powered for infants aged < 6 months and the number of such infants recruited is NR

Attrition/dropout: NR separately for the 0–6 month age group. Overall, this did not differ between the groups: two children in each group died, two children were discharged on request in the WHO group, three in the ICMH group and one child absconded in the WHO group

General comments

Generalisability: difficult to assess generalisability because the numbers of children aged 0–6 months are not known

Outcome measures: only one outcome measure, weight gain, reported for the 0–6 month age group

Intercentre variability: two centres, but each was applying a different protocol. Unclear how differences between the two centres, other than the different protocols, might have influenced the results

Conflict of interest: no competing interests are stated by the report authors

	ICMH protocol	**WHO protocol**
Management	No phasing	Divided into two phases: initial and rehabilitation phase as per WHO 1999 guidelines.[10] Reference provided but no details; those below obtained from original WHO paper[10]
	Identification of life-threatening problems, and management of unconsciousness, convulsion, hypothermia and hypoglycaemia done according to the WHO protocol for both groups	
Correction of electrolyte imbalance and micronutrients deficiencies	Locally available minerals and trace elements as below	Added to F75 and F100 formula at concentrations noted below
Potassium	Potassium chloride 5 mmol/kg/day	F75: 3.6 mmol per 100 ml
		F100: 5.9 mmol per 100 ml
Magnesium	Magnesium sulphate 10 mg/kg/day	F75: 0.43 mmol per 100 ml
		F100: 0.73 mmol per 100 ml
Sodium	NR	F75: 0.6 mmol per 100 ml
		F100: 1.9 mmol per 100 ml
Zinc	Zinc sulphate 2 mg/kg/day	F75: 2.0 mg per 100 ml
		F100: 2.3 mg per 100 ml
Folic acid	2.5 mg/day	5 mg of folic acid on day 1 and then 1 mg per day thereafter. Folic acid also present in vitamin mix 0.35 mg per litre of liquid diet
Multivitamins	0.6 ml/day orally (composition per 0.6 ml of multivitamin: vitamin D1, 200 IU, thiamine 1 mg, riboflavin 1 mg, pyridoxine 1 mg, panthenol 2 mg, nicotinamide 5 mg and vitamin C 60 mg)	Added to liquid diet in all phases of treatment [per litre of liquid diet: thiamine 0.7 mg, riboflavin 2.0 mg, nicotinic acid 10 mg, pyridoxine 0.7 mg, cyanocobalamin (vitamin B12) 1 µg, vitamin C 100 mg pantothenic acid 3 mg, biotin 0.1 mg, retinol (vitamin A) 1.5 mg, calciferol (vitamin D) 30 µg, vitamin E 22 mg and vitamin K 40 µg]
Copper	Not available in the local market for use	F75: 0.25 mg per 100 ml
		F100: 0.25 mg per 100 ml

Iron	Supplementation (6 mg/kg/day) was started on the 15th day	Iron should *never* be given during the initial phase of treatment. During the rehabilitation phase, children with moderate or severe anaemia were given elemental iron orally, 3 mg/kg per day in two divided doses, up to a maximum of 60 mg daily, for 3 months
Severe anaemia	Blood transfusion given (with or without heart failure)	Blood transfusion given
Vitamin A supplement	Every child	For all children, given orally < 6 months of age 50,000 IU 6–12 months of age 100,000 IU > 12 months of age 200,000 IU For those with clinical signs of vitamin A deficiency dose as above given on the first 2 days, followed by a third dose at least 2 weeks later
Antibiotics	As recommended by WHO for both groups	
Feeds	Made using whole cow's milk, sugar, soya oil and water to provide 100 kcal in 100 ml/kg/day administered every 2 hours during day and night. If the child wanted more than the prescribed diet, extra family food was given ad libitum and breastfeeding was encouraged	Two formula diets, F75 and F100, are used made from dried skimmed milk, sugar, cereal flour, vegetable oil, mineral and vitamin mixes. F75 (75 kcal th or 315 kJ/100 ml), is used during the initial phase of treatment, whereas F100 (100 kcal th or 420 kJ/100 ml) is used during the rehabilitation phase, after the appetite has returned
Play therapy, nutrition education and discharge criteria	Similar to those for children in the WHO group	

IU, international units; NR, not reported.