

For publication as web appendix only:

Methods: Duplicate visits were performed by a study supervisor in 10% of visits as a quality control measure. Field workers records were verified by study medical officer weekly before entering the data in the computer. Viability testing of the probiotics sachets collected from the field sites was done. A schedule for collection of these sachets was prepared such that every week 4 sachets were collected in reverse cold chain from infants who were in 1-4th week of follow up, over a six month period. These sachets were transported to an external lab (Micro s.r.l., Italy, accredited by SINAL [National System for accreditation of laboratories, Italy] and the International Laboratory accreditations cooperation ILAL-MRA]. The certificate of analysis received from the lab certified the adequacy of cell counts in the sachets, and based on the results extended the expiry of the batch by one year. All case record forms were cross-checked by supervisors and medical officers before being sent for double data entry in EPI Info version 6.0) with built in range and consistency checks. Hand checking on random samples was done and frequency distribution of important variables examined periodically to identify aberrant values. A program file developed in EPI 6 platform was run, the list of errors was sent to the sites for corrections.

IMNCI Algorithm: Presence of any of the following signs suggested possible serious bacterial infection: convulsions or fast breathing (60 breaths per minute or more); severe chest in-drawing or nasal flaring or grunting; 10 or more skin pustules or a large boil; axillary temperature 37.5 Celsius or above (or feels hot to touch); temperature less than 35.4 Celcius (or feels cold to touch); lethargic or unconscious or less than normal movements. (Ref: Training Modules 1 to 9 - Unicef. www.unicef.org/india/Training_Module_1-9.)