the purpose of this description is not clear. The Methods section makes it clear that the decision of the pediatrician in the OPD/emergency (Study person B) without access to laboratory tests was the gold standard and Study person A's clinical signs were compared against this gold standard. The primary diagnoses reported in both studies were all purely clinical diagnoses. All this is perfectly acceptable, but in that case, the laboratory investigations done after admission and hospital course were of no relevance to the study question. It would have been a different story if the "need for urgent hospitalization" was assessed retrospectively taking into account laboratory tests, course and pediatrician decision. As things stand, we do not know what were the final diagnoses made after investigations and how often the decision to admit was itself wrong or questionable.

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Reply

These two papers are part of the multicentric WHO study on signs of severe illness in young infants. Hence, a lot of data especially related to multi-variate analysis incorporating numerous predictors including low birth weight is not depicted in the papers. Similarly, the sensitivity and specificity data has been left out by the editors because of constraints of space. The main paper is being published in The Lancet soon and couple of supplementary papers shall follow.

At the Delhi site, 748 exclusions were made because of following reasons: needed immediate resuscitation 19, outside study area 259, hospitalized in previous two weeks 163, received prior treatment 184, previously participated in study 152, congenital malformations 2 and refused consent 25 (some infants excluded for more than one reason). This information is missing from the text box in the figure because of formatting error and this account for the discrepancy in numbers.

It is true that special arrangements were made to run the "OPD" till 9 pm for the study. This was done to imitate the ground realty of infants reporting sick any time of the day. This special "OPD" was physically located in the emergency for logistic reasons at Chandigarh while at Delhi site during 9-11.30 am , these infants presented in the OPD or emergency ward from casualty as per hospital existing policies. A logbook was maintained to register all eligible infants. However, the infants coming to emergency in a state needing cardio-pulmonary resuscitation were not included.

Ideally, one would have liked to conduct this study in the community itself. However, it was not possible to do such a large scale study at multiple sites in the community because of technical and logistic constraints of obtaining a gold standard assessment in the community, the risk of contamination of findings between the two observers performing clinical evaluations and the inability to validate their assessments in the community. So, a simulation was done by choosing a place as close to the community as possible –at first line health care facilities which work like First Referral Units and where parents have free access to walk in with any kind of complaints. This is also reflected in the pattern of morbidities seen in the infants reporting to both these sites (*Tables* II and III of Delhi paper and *Tables* I and III of Chandigarh paper) which mimics that expected in the community. The first contact person was a nurse with GNM or ANM qualifications who "had not worked in leading hospital". This is akin to the real

life health worker who would be expected to see the infant in the community. A short period of training and re-orientation was done as requirement for a research study, to ensure uniformity and consistency in their assessment. However these ANM's/GNM's are expected to be fully trained in routine to perform these simple assessments.

Pulse oximetry was done by the study person B in all enrolled infants after completing the physical examination. He could use the information as an aid for making decisions. In the modern era of medicine, one would expect pulse oximeter to be ultimately available at all first referral units. This gadget was available at all sites and uniform methods were adopted by study persons B across all sites for making a decision regarding "need for admission". If indicated, initial laboratory investigations (serum bilirubin, glucose, chest *x*-ray) were done and a decision was taken within two hours by study person B for need of hospitalization. The quality of the diagnoses being made by study person B was ensured by an initial period of training, creating a manual of operations with standard definitions and an ongoing review of case records by a committee of senior investigators (pediatricians with more than 15 years experience) with regular feedbacks. For this purpose complete case records along with all relevant investigations were taken into consideration for providing feedback to study person B.

In addition, one of the useful secondary objectives of the study was to document in detail and precisely the possible range of specific diagnosis encountered at first referral units in infants <2 months of age. Hence, laboratory investigations were necessary to confirm the diagnoses and have reliable information.

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False Positive HIV -1 DNA PCR in Infancy

The prevalence of HIV infection in antenatal population in India ranges from .08% to 5%. As the rate of perinatal transmission is about 30%, it can be estimated that 56,700 newborns are infected with HIV each year(1). The seroprevalence among antenatal women is the most important indicator of prevailing HIV infection in the community. In this study 1768 pregnant women who attended the antenatal clinic at Sir Sundar Lal Hospital, Banaras Hindu University from March 2005 to August 2006 were screened for HIV infection after obtaining informed consent. Of these, 17 were HIV infected, indicating a seroprevalence of 0.96% which is alarmingly close to 1%, the benchmark for high prevalence.

Five of the HIV infected women consented for medical termination of pregnancy and 12 delivered during the study period in the hospital. Antiretroviral prophylaxis in pregnant women was based on CD4 counts, affordability and gestational age. 5 pregnant women with CD4 counts more than 250/μL (mean 428.7/μL) were offered protease inhibitor based HAART whereas 3 of them with CD4 counts less than 250/μL received two nucleoside reverse transcriptase inhibitor and nevirapine. Four were administered single dose nevirapine at the time of delivery. Zidovudine was included in the regimen in patients with hemoglobin more than 8 g/dL Except one, all were delivered by cesarean section. Newborns received single dose Nevirapine within 72 hours of birth. Mothers were counseled regarding risks of breastfeeding versus top feeding and none was breastfed. HIV DNA PCR was performed twice to diagnose infection in neonates. First test was performed within 48 hours and the second was performed at about 6 weeks. PCR results were positive for HIV virus in 3 neonates. These infants on follow up were asymptomatic and 4 have been tested at 18 months using HIV ELISA with two different antigen tests and one rapid test to confirm the diagnosis.