

Signs of Severe Illness in Young Infants

Deorari, *et al.*(1) and Narang, *et al.*(2) have published their respective site-specific data from the recently concluded multi-centric study on signs of severe illness in young infants(1). The meticulousness with which these 2 sites have conducted their studies is commendable. This correspondence is regarding certain issues in both papers.

In the study from Delhi, all the 1626 triaged patients are not accounted for. If one adds the excluded patients ($n=487$) to the ones enrolled ($n=878$), it totals to 1365. It is not clear what happened to the remaining 261 patients. Despite the fact that the 2 studies followed an identical protocol, the Chandigarh site excluded a large number of subjects under headings that do not even figure in the Delhi study: quota filled for the day ($n=355$), scheduled visit ($n=383$) and revisit ($n=183$). If it were true that the Delhi study did not exclude these categories, it would mean that their study population had a larger proportion of patients who had no obvious on-going sickness (scheduled visit, revisit). The non-exclusion of such patients could result in spuriously better odds ratios and predictive values in Delhi compared to Chandigarh.

In the paper from Delhi, there is some confusion about the source of the subjects. It was reported in Methods that all eligible subjects presented to the outpatient department (OPD); the study hours were 9 am to 9 pm; and infants brought outside study hours were referred to emergency. This implies that the OPD at the Delhi hospital was functioning until 9 pm for this study (possible, but highly improbable), with none of the enrolled subjects being recruited through the emergency. It is important for both sites to mention how many patients were recruited from emergency versus OPD and to analyze these sub-groups separately. Self-referred patients coming to the emergency are qualitatively different from those coming to the

OPD in their health seeking behaviors as well as the nature and seriousness of their illnesses. In addition, the manner in which the study personnel interpret the history and clinical signs and decide on admission may vary depending on whether the same patient presents to the OPD or to the emergency. These differences could alter the association between clinical signs and the decision to admit.

Although low birth weight was not evaluated by either group as a clinical predictor *vis-à-vis* admission for severe illness, one hopes it will be ultimately incorporated in a multivariate model (particularly for 0-6 days). Birth weight not only influences a pediatrician's decision to admit but it may interact with other predictors of severe illness that emerged significant on univariate analysis.

I have concerns about the applicability of the conclusions to peripheral health workers. It is difficult to believe that a staff nurse, who worked in a leading hospital in a metropolis and received one-month training with video demonstrations, case discussions and didactic classes, could be equated to a peripheral health worker in terms of ability to pick up clinical signs. As far as possible, the "Study person A" ought to have resembled the real-life health worker in terms of qualifications and training.

Authors at both sites have discussed about the sensitivity, specificity and predictive values of the signs in the Discussion, but data regarding these parameters have not been provided in the results. A high odds ratio does not automatically imply a high sensitivity or predictive value.

It appears from Methods that all enrolled subjects (not just admitted ones) underwent pulse oximetry. Does this mean that pulse oximetry was being done in the OPD and was this information available to Study person B when she decided on need for urgent admission? This is not a standard of care for deciding admissions.

Laboratory investigations and hospital course of admitted patients have been described in detail, but

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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REFERENCES

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2. Narang A, Kumar P, Narang R, Ray P, Carlin JB, Greenwood P, *et al.* Clinico-epidemiological profile and validation of symptoms and signs of severe illness in young infants (<60 days) reporting to a district hospital. *Indian Pediatr* 2007; 44: 751-759.

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 multivariate 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 reality 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