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Evaluation of Indian Adaptation of Integrated Management of Neonatal and Childhood Illness (IMNCI) algorithm: A Prospective Study from Tertiary Care Institute of Haryana

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Abstract

Background: Every year more than 12.9 million children die in developing countries before they reach their fifth birthday. Seven out of ten deaths are due to acute respiratory infections (mostly due to pneumonia), diarrhea, measles, malaria, malnutrition and are often a combination of these illnesses. In India, nearly 17 lakh group children death occur each year and childhood mortality rate is one of the highest mortality in the world. The Government of India recognized the need to strengthen child-health activities in the country and decided to launch IMCI

Materials: Present study was carried in Department of Pediatrics at Pt. B.D. Sharma, Post Graduate Institute of Medical Sciences, Rohtak from August 2010 to January 2012 and included 500 500 children of which 250 children were aged 0-2 months and rest 250 children were aged 2- 59 months, were included in the study.

Results: Among the children enrolled as per IMNCI, possible serious bacterial infection (69%) was the most common cause of morbidity, followed by jaundice (20.8%) and very low weight (14.4%). **Discussion/summary:** The overall mortality in our study subjects was 14 (2.8%) with highest in 0-7 days age group [9 (6.5%)]. Out of these 14 cases, 5 (35.7%) were mismatched and 3 (21.4%) were undiagnosed by IMNCI algorithm.

Keywords: Children, Mortality, Infections.

Introduction

Every year more than 12.9 million children die in developing countries before they reach their fifth birthday. Seven out of ten deaths are due to acute respiratory infections (mostly due to pneumonia), diarrhea, measles, malaria, malnutrition and are often a combination of these illnesses [1]. In response to this challenge World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) launched the global initiative of "Integrated Management of Childhood Illness" (IMCI) in 1992 with the aim of improving management of childhood morbidity and mortality [2]. It was combined with assessment and management of nutritional and immunization status of the child and maternal health care.

In India, nearly 17 lakh group children death occur each year and childhood mortality rate is one of the highest mortality in the world. The Government of India recognized the need to strengthen child-health activities in the country and decided to launch IMCI. A core group was constituted comprising representatives from Indian Academy of Pediatrics (IAP), National Neonatology Forum of India (NNF), National Anti-Malaria Program (NAMP), Department of Women and Child Development (DWCD), Child-in Need Institute (CINI), WHO, UNICEF, eminent pediatricians, neonatologists and the representatives from the Ministry of Health and Family Welfare, Government of India. The generic IMCI guidelines were adapted as such and later modified in 2002 which included new born care and this was named as Integrated Management of Neonatal and Childhood Illness (IMNCI) [3].

Rather than making a diagnosis, IMNCI practitioners classify the child's illness on the basis of syndromic approach and using various algorithms and predefined treatments. IMNCI guidelines focus around a series of simple questions, easily recognized symptoms and signs, with special emphasis on nutrition, health promotion and counseling.

There are limited studies on applicability of IMCI/IMNCI in India. Most of studies for the validity of IMCI have been done in African countries [5, 6, 7, 8]. There is also paucity of published experience with the IMNCI approach from the Indian subcontinent [9, 10].

However, with Indian adaptations of IMCI algorithm and the phases for training all categories of health workers in its use, it is imperative that we have more experience with its use in Indian conditions. The present study was therefore designed to compare physician's diagnosis with IMNCI diagnosis in children between 0-59 months of age, attending a tertiary care center in Northern India with at least one IMNCI general danger sign to validate the IMNCI algorithm in a hospital setting.

Materials and Methods: Study setting and study period:

Present study was carried in Department of Pediatrics at Pt. B.D. Sharma, Post Graduate Institute of Medical Sciences, Rohtak. Ethical clearance as per hospital policy was taken.

Study Design:

Prospective study

Study Period:

From August 2010 to January 2012.

Sample Size:

A total of 500 children of which 250 children were aged 0-2 months and rest 250 children were aged 2- 59 months, were included in the study.

Inclusion Criteria:

Children from 0- 59 months of age presented to the outpatient department and emergency room for the first time.

Exclusion Criteria:

Children who came for immunization, having trauma or surgical problem and those who were already on any kind of medical treatment were excluded from study.

Method:

A single Pediatric resident doctor examined the children for the presence of general danger signs. Patients were also assessed for the presence of malnutrition and anemia. Children recruited in the study were assessed and classified according to IMNCI. These were termed as "IMNCI diagnoses". The child was then reassessed, examined, investigated and managed by the concerned unit as per their protocol. Information was collected as per proforma.

A detailed history was taken for each subject and clinical examination was performed. All relevant investigations as per requirement including hemoglobin, blood counts, C- reactive protein, serum bilirubin, peripheral smear for malarial parasite, urine examination, stool examination, chest radiograph, blood culture, lumbar puncture etc. were performed. The final diagnosis was made and therapy was instituted according to institutional protocol. This diagnosis was taken as "gold standard" and was compared with IMNCI algorithm. The study children were either admitted or sent home after initial evaluation, depending upon the nature and severity of illness. Each unimmunized or incompletely immunized sick child was immunized and dietary therapy/ advice was given to every child as needed. Hospitalized children were followed up till discharge or death. Other children were asked to report for routine follow up (3 to 7 days later) to determine the final outcome.

Since the gold standard criteria had different categories of diagnosis, to make it comparable with IMNCI classification, in 0-2 months group, Possible Serious Bacterial Infection includes Early Onset Sepsis, Late Onset Sepsis, clinical sepsis, pneumonia and meningitis. Diagnosis of jaundice includes both mild- moderate jaundice. While in 2- 59 months group, pneumonia included all cases of convalescent bronchopneumonia while severe pneumonia included lobar pneumonia, bronchopneumonia. Similarly, Very severe febrile disease of IMCI classification included septicemia, meningitis, meningo-encephalitis, encephalitis, enteric fever and hepatitis. Very low weight category included all cases of Protein Energy Malnutrition (PEM) Grade I, II and III and severe malnutrition group included PEM Grade IV, marasmus, Kwashiorkor or marasmic Kwashiorkor. "Some" anemia of IMCI included mild and moderate anemia of gold standard.

Statistical Analysis:

The study subjects were first analyzed separately as 0-2 months and 2- 59 months age groups. The 0-2 months age group was further divided into 0-7 days and 7 days-2 months age group and analysis of these sub-groups was done. The data was entered in Microsoft Excel® and analysis was done using SPSS® software version 16. Other standard statistical tests performed included Fischer's exact test, Chi-square test, odd's ratio, p value, sensitivity, specificity, positive predictive value and negative predictive value. Two categories of possible diagnosis and treatment were available for each recruited study subject, namely 'Gold Standard and IMNCI algorithm'. The diagnostic agreement between the 'Gold Standard and IMNCI' was compared. The utility of reference criteria to predict admission was also evaluated to compute sensitivity and specificity of the algorithm.

Results:

Age and Sex distribution:

Five hundred children were enrolled in the present study, out of which 250 patients were aged between 0-2 months (group A) and another 250 were between 2- 59 months of age (group B). In group A, 139 children were aged between 0-7 days (group A1) and 111 children were aged between 7 days- 2 months (group A2). The distribution is depicted in figure 1. Among 500 study subjects, there were 333 (66.6%) males and 167 (33.4%) females.

Enrollment of study subjects:

146 (29.2%) children were recruited from OPD and rest 354 (70.8%) children were enrolled from emergency room. In group-A1, 27 (19.4%) were recruited from OPD and 112 (80.6%) from emergency room. In group-A2, 41 (37%) were

from OPD and 70 (63%) from emergency room. In group B, 78 (31.2%) were from OPD and 172 (68.8%) from emergency room. In group A1, 137 (98.6%) were advised admission and 2 (1.4%) were sent home after initial evaluation. In group A2, 104 (93.7%) were advised admission and 7 (6.3%) were sent home. While in group B, 194 (77.6%) were advised admission and 56 (22.4%) were sent home.

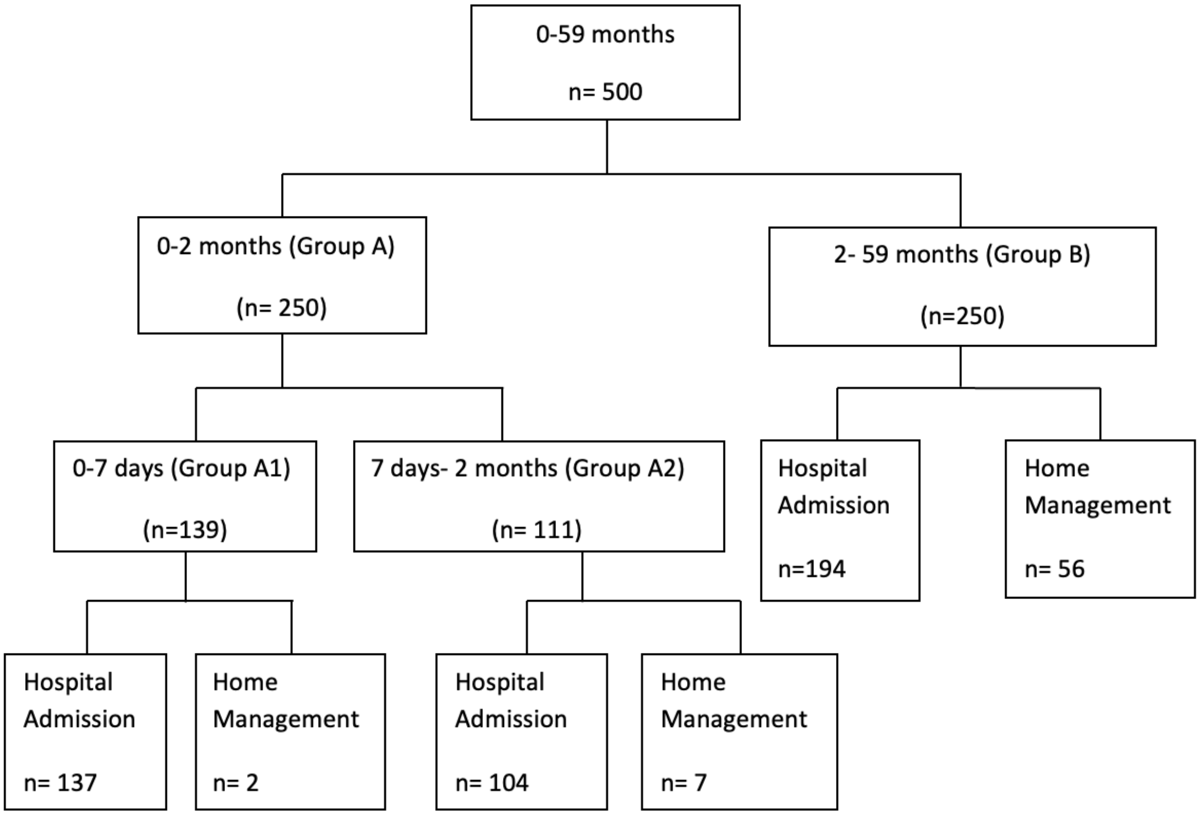


Figure 1: Figure depicting the enrollment of study subjects.

Morbidity among enrolled Study Subjects:

Out of 500 children, 320 (64%) had a single illness and rest 180 (36%) had two or more co-existent illnesses as per IMNCI algorithm. Mean number of illnesses per child in IMNCI and Gold Standard were depicted in Table 1. Total number of illnesses were 156 (0- 7 days), 180 (7 days- 2 months) and 307 (2- 59 months) as per IMNCI. Similarly total number of illnesses as per Gold Standard were 181 (0- 7 days), 163 (7 days- 2 months) and 331 (2- 59 months).

Table 1: Mean Illnesses per Child in Different Age Groups in IMNCI and Gold Standard

Mean no. of illnesses	**0-7 days n=139**	**7 days-2 months n=111**	**2– 59 months n=250**
IMNCI	1.31	1.62	1.36
Gold Standard	1.3	1.47	1.32

Baseline Characteristics:

Group A1 (0- 7 days):

A total of 139 children were enrolled in group A1. The baseline characteristics are depicted in Table 2. Mean (SD) weight of enrolled children was 2.37 (0.67) kg. There were 67 (48.2%) low birth weight children (birth weight <2.5 kg) and 38 (27.34%) were preterm children (gestational age <37 completed weeks).

Table 2: Baseline characters of Study Subjects in Group A1 (n=139)

Baseline character		**No. (%)**
Sex	Male	96 (69%)
	Female	43 (31%)
Weight (kgs)	< 1.5	19 (13.67%)
	1.5-2.5	48 (34.53%)
	>2.5	72 (51.8%)
Gestation (wks)	<32	13 (9.4%)
	32-37	25 (18%)
	>37	101 (72.7%)

Morbidities in children (IMNCI Vs Gold Standard):

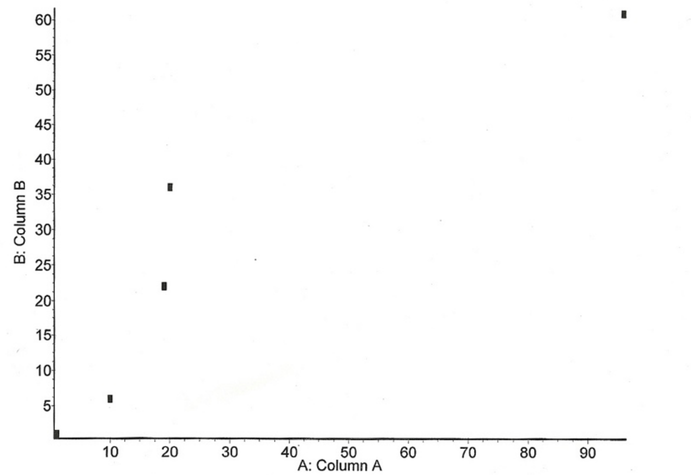
Group A1 (0- 7 days):

Among the children enrolled as per IMNCI, Possible serious bacterial infection (69%) was the most common cause of morbidity, followed by jaundice (20.8%) and very low weight (14.4%) (Table 3). There was no child with diarrheal illness in this age group. Similarly in Gold Standard group, sepsis, meningitis and pneumonia which were clubbed as Possible serious bacterial infection (43.9%) was the most common cause of morbidity. The illnesses which were diagnosed by the physician (Gold Standard) but excluded in the IMNCI were Birth asphyxia with Hypoxic Ischemic Encephalopathy (HIE) (23%), Birth asphyxia with no HIE (12.2%), Transient Tachypnea of Newborn (TTN) (17.3%), Respiratory Distress Syndrome (RDS) (4.3%) and others (3.65%). Others included Hemolytic disease of newborn (HMD) (2), kernicterus (1), Congenital Talipes Equino Varus (CTEV) and (1), Cephalohematoma (1). The correlation coefficient (r) was 0.9107 between IMNCI and Gold Standard diagnoses (95% CI = 0.145-1, *p* value= 0.032).

Table 3: Comparison of Morbidities: 'IMNCI' vs 'Gold Standard'

Group A1 (n=139)

Illness	**IMNCI**	**GOLD STANDARD**
Possible Serious Bacterial Infections(PSBI)	96 (69%)	61 (43.9%)
Local bacterial infections	1(0.72%)	1(0.7%)
Severe jaundice	10(7.2%)	6(4.3%0
Mild to moderate jaundice	19(13.6%)	22(15.8%)
Very low weight(VLW) for age	20(14.4%)	36(25.9%)



Graph 1: Showing Correlation Between IMNCI (Column A) And Gold Standard (Column B) Diagnoses In 0- 7 Days Age Group.

Comparison of IMNCI with Gold Standard in Infant 0- 7 days age

Sepsis:

Table 4 shows that diagnostic accuracy of sepsis as per IMNCI was as high as 95.1% (58/61). Hence IMNCI is a highly sensitive algorithm for detection of sepsis but lacks specificity (4.8%). The detection of sepsis by IMNCI algorithm in age group of 0- 7 days is significantly higher as compared to Gold Standard (OR= 13.5 (95% CI = 5.06 – 36.0), *p<0.01*).

Table 4: Diagnostic accuracy of IMNCI algorithm regarding Sepsis as compared to Gold Standard Group A1 (n=139)

	Gold Standard		**Total**
	Sepsis	No Sepsis	
IMNCI- Sepsis	58	40	98
IMNCI- No Sepsis	3	2	5
Total	61	42	103

Sensitivity = 95.1%
Specificity = 4.8%
PPV = 59.2%
NPV = 40%

Comparison of IMNCI with Gold Standard in Infant 0- 7 days age

Severe Jaundice:

Table 5 shows that diagnostic accuracy of severe jaundice as per IMNCI was as high as 100% (6/6). Hence IMNCI is a highly sensitive algorithm for detection of jaundice. The detection of severe jaundice by IMNCI algorithm in age group of 0- 7 days is higher as compared to Gold Standard (OR= 2.018 (95% CI = 0.62-6.57), *p=0.378*).

Table 5: Diagnostic accuracy of IMNCI algorithm regarding severe jaundice as compared to Gold Standard

Group A1 (n=139)

	Gold Standard		**Total**
	Severe Jaundice	No Severe Jaundice	
IMNCI- Severe Jaundice	6	4	10
IMNCI- No Severe Jaundice	0	19	19
Total	6	23	29

Sensitivity = 100%
Specificity = 82.6%
PPV = 60%
NPV = 100%

Comparison of IMNCI with Gold Standard in Infant 0- 7 days age
Not able to feed:
Table 6 shows that diagnostic accuracy of "Not able to feed" as per IMNCI was as high as 100% (6/6). Hence IMNCI is a highly sensitive algorithm for detection of "Not able to feed". The detection of "Not able to feed" by IMNCI algorithm in age group of 0- 7 days is higher as compared to Gold Standard (OR= 1.467 (95% CI = 0.433- 4.967, *p=0.75*).

Table 6: Diagnostic accuracy of IMNCI algorithm regarding Not able to feed in as compared to Gold Standard

Group A1 (n= 139)

	Gold Standard		**Total**
	Not able to feed	Able to feed	
IMNCI- Not able to feed	6	2	8
IMNCI- Able to feed	0	20	20
Total	6	22	28

Sensitivity = 100,
Specificity = 91%
PPV = 75%
NPV = 100%

Comparison of IMNCI with Gold Standard in Infant 0- 7 days age
Referral Criteria:
Table 7 shows that diagnostic accuracy of referral criteria as per IMNCI was as high as 97.5% (78/80). Hence IMNCI is a highly sensitive algorithm for detection of referral cases but lacks specificity (49.2%). The detection of referral cases by IMNCI algorithm in age group of 0- 7 days is significantly higher as compared to Gold Standard (OR= 2.57 (95% CI = 1.52- 4.33, *p <0.01*).

Table 7: Diagnostic accuracy of IMNCI algorithm for Children Requiring Referral/ Hospital Admission as compared to Gold Standard

Group A1 (n= 139)

IMNCI	**Gold Standard**		**Total**
	Referral	No Referral	
Referral	78	30	108
No Referral	2	29	31
Total	80	59	139

Sensitivity = 97.5%
Specificity = 49.2%
PPV = 72.2%
NPV = 93.6%

Disease specific matching of diagnosis between IMNCI and Gold Standard in 0-7 days

Table 8 shows that most of the mismatch was in the diagnosis of birth asphyxia, hypoxic ischemic encephalopathy, transient tachypnea of newborn, hyaline membrane disease etc. While in 'no diagnosis' category, most of the cases were of birth asphyxia, hypoxic ischemic encephalopathy and premature/low birth weight. In cases of sepsis and jaundice, there were very few mismatches.

Discussion:

The present study was designed to validate the utility of IMNCI protocol when compared to physician protocol. Out of 500 children 320 (64%) had a single morbidity and 180 (36%) had two or more than two co-morbidities. The diagnostic sensitivity and specificity of IMNCI algorithm in infants aged 0- 7 days for various diseases were as: sepsis (95.1% and 4.8%), jaundice (100% and 82.6%) and not able to feed (100% and 91%).

Group A1 (0- 7 days):

In our study mean number of illnesses was same in both IMNCI and Gold standard (1.31 and 1.3, respectively). Similar studies conducted by Kaur *et al.* [9] and Goswami *et al.* [10] showed difference in mean illnesses between IMNCI and Gold standard (1.88 vs 2.14 and 1.67 vs 1.97, respectively). This can be due to observer bias as the working pediatric resident was aware of the diagnosis made by gold standard.

There were 67 (48.2%) low birth weight and 38 (27.34%) preterm children in our study group. Kaur *et al.* [9] showed 29.6% of low birth weight infants in their study group which is comparable with our findings. There was no category for low birth weight and preterm infants in IMNCI algorithm and because low birth weight and prematurity are significant risk factors for morbidity and mortality in newborns, the inclusion of these criterions in IMNCI algorithm is evident. No study is available for comparison of these findings.

Among the children enrolled as per IMNCI, possible serious bacterial infection (69%) was the most common cause of morbidity, followed by jaundice (20.8%) and very low weight (14.4%). In the study by Kaur *et al.* [9], morbidity profile was different with higher number of jaundice (50.6%) and very low weight (48.9%) and lower number of possible serious bacterial infections (47.2%). This difference may be due to different study population in our study group.

The illnesses which were diagnosed by the physician (Gold Standard) but excluded in the IMNCI were birth asphyxia with hypoxic ischemic encephalopathy (HIE) (23%), birth asphyxia with no HIE (12.2%), transient tachypnea of newborn (TTN) (17.3%), respiratory distress syndrome (RDS) (4.3%) and others (3.65%). Kaur *et al.* [9] also found similar results with slightly lower birth asphyxia with hypoxic ischemic encephalopathy (18.8%) and transient tachypnea of newborn (2.3%).

The sensitivity and specificity of serious bacterial infections were 95.1% and 4.8% (OR= 13.5 (95% CI = 5.06 – 36.0), $p<0.01$). The studies conducted by Kaur *et al.* [9] and Goswami *et al.* [10] also found similar sensitivity (88.5% and 96-98%, respectively) but differed in specificity (57.4% and 80-92%, respectively). The difference in specificity may be due to high number of mismatches in sepsis in our study (40%). IMNCI algorithm was found good in the diagnosis of jaundice and not able to feed categories.

The sensitivity and specificity of referral criteria were 97.5% and 49.2% in our study. The sensitivity and specificity found in studies by Kaur *et al.* [9] and Goswami *et al.* [10] were 97%, 85% and 78.5%, 78.6%, respectively. The difference in specificity was mainly due to overdiagnosis of sepsis by IMNCI in our study.

The diagnostic mismatch was 38.7% in our study. This was comparable with studies by Kaur *et al.* [9] and Goswami *et al.* [10] in whom the mismatches were 31.3% and 42.7%, respectively. Hypoxic ischemic encephalopathy (31%) and transient tachypnea of newborn (33.8%) were the main illnesses in our mismatches. While Kaur *et al.* [9] found hypoxic ischemic encephalopathy (38.7%) and meconium aspiration syndrome (13.7%) as the main illnesses for mismatches.

In our study newborns presented with delayed cry were 16 (11.5%) out of which 10 (62.5%) developed hypoxic ischemic encephalopathy. Hypoxic ischemic encephalopathy was among the leading causes of mortality in newborns. Therefore inclusion of delayed cry as referral criteria in IMNCI algorithm for young infants (0-2 months) should be considered as evident. There are no comparative studies available.

Recommendations

1. In view of very high mismatches between IMNCI and Gold Standard in the diagnosis of sepsis in 0-2 months age group (more in 0- 7 days) and malaria in 2- 59 months age group, IMNCI algorithm has to be refined for appropriate management of these conditions.
2. Signs/symptoms like low birth weight (incidence 31%), preterm (incidence 21%) and delay cry (incidence 5%) should be included as a referral criteria in IMNCI algorithm for 0-2 months.
3. Respiratory illnesses like bronchiolitis, asthma which come under yellow or green category and are being over treated should be redefined in IMNCI algorithm.
4. Conditions like poisoning (incidence 36.5%), environmental hazards (incidence 10%) should be included as a referral criteria in IMNCI algorithm.
5. Overall IMNCI algorithm appears to be a promising, feasible and useful intervention strategy to diagnose children with severe illnesses in 0-2 months and 2- 59 months age group.

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