NEONATAL RESUSCITATION PROGRAM

ASSESSMENT OF MONITORING OF CLINICAL OUTCOMES: SECOND ROUND DATA

AMERICAN INTERNATIONAL HEALTH ALLIANCE

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Table of Contents

LIST OF ACRONYMS AND ABBREVIATIONS

AAP	American Academy of Pediatrics
AHA	American Heart Association
AIHA	American International Health Alliance
CNS	Central Nervous System
HFH	Henry Ford Hospital
MAS	Meconium Aspiration Syndrome
NIS	New Independent States
NRP	Neonatal Resuscitation Program
NRP TC	Neonatal Resuscitation Program Training Center
PPV	Positive Pressure Ventilation
RDS	Respiratory Distress Syndrome
USAID	United States Agency for International Development

I. EXECUTIVE SUMMARY

In 2003, a second round of data on the Neonatal Resuscitation Program (NRP) in the New Independent States was collected and analyzed. The objective was to refine the first round process of monitoring clinical outcomes and to use the data systematically for the purpose of quality assurance. Data was obtained from 16 Neonatal Resuscitation Training Centers (NRTCs) and 64 hospitals, covering a total of 8,386 infants.

The methodology for the second round was adapted from the first round to give more precise diagnostic definitions and to account for the expansion of NRP training in the region. There are methodological limitations in the first and second round studies, principally the lack of a control group for comparing the effect of training. Other limitations relate to different sample populations, the confounding effects of limited supplies at NIS hospitals, and the introduction of subjective bias in diagnosis and Apgar scoring.

In the first round study, the critical percentage of trained staff was found to be 25% of all medical staff. The findings were that clinical outcomes for infants were significantly better at institutions where 25% of the staff had been trained in NRP. The findings were valid across a range of conditions and for all infants, whether they required resuscitation or not. The findings remained valid when case risk was controlled for by excluding data from level I hospitals, which have a lower-risk population.

In the second round study, the distinction between more than and less than 25% of medical staff trained was no longer applicable. Clinical outcomes for infants were not significantly different in the two groups. This was considered to be due to the general adoption of NRP practices in the NIS by the time data was collected in the second round. The institutions were then grouped by 100% of neonatologists trained and less than 100% of neonatologists trained. This distinction yielded statistically significant differences in outcomes.

The findings were that there was an improvement in Apgar scores between 1 minute and 5 minutes of life in hospitals with 100% trained neonatologists, though there was not a statistically significant difference between hospitals with 100% trained and less than 100% trained neonatologists. A clear difference emerged between the 100% and less than 100% groups when neonatal morbidities and mortalities in several categories were compared. In hospitals where 100% of neonatologists were trained, there was a reduction in RDS, MAS, death due to perinatal asphyxia, death due to RDS, and death due to MAS. The reduction in CNS abnormalities was not statistically significant. These results remained consistent when controlling for the effects of gestational age, severity of infant's condition at birth, and the level of the hospital.

The results of the two studies covering 15,000 infants were consistent and support the positive effect of organized NRP training on morbidity and mortality of infants. In the first study, the percentage of all medical staff trained was linked to improved outcomes. In the second study, the training of the key medical staff member, the neonatologist, was linked to improved outcomes. The finding indicates that the critical factor in improving outcomes for infants in the current circumstances in the NIS is training 100% of neonatologists in NRP.

II. INTRODUCTION

Under a cooperative agreement with the United States Agency for International Development (USAID), the American International Health Alliance (AIHA) developed a program of partnerships between institutions in the U.S. and the New Independent States (NIS). Many of the partnerships as well as other organizations focused on improving care to women and newborns, including basic resuscitation of infants as a core component of educational activities. The American Academy of Pediatrics/American Heart

Association's (AAP/AHA) Neonatal Resuscitation Program (NRP) was the foundation for this training. Over time, the participants recognized that in order to improve neonatal health outcomes and measure such improvements, a standardized approach to the NRP training was needed. AIHA funded the initiative and since 1997, 17 NRTCs have been established in six countries of the former Soviet Union.

This assessment presents the results of the second round of data related to clinical outcome monitoring and summarizes the results of the first round. The second round data was collected in 2003 and the first round data was collected in 2001. The studies were conducted by Dr. Sudhakar Ezhuthachan and Ms. Christine Newman of Henry Ford Hospital (HFH) and Dr. Dmytro Dobryanskyy of L'viv Oblast Hospital in Ukraine.

III. OBJECTIVES

A three-pronged approach to quality monitoring of the NRP program was used:

- Monitoring ***course standards*** or implementation of the course through course evaluations and co-teaching by US or NIS instructors;
- Monitoring ***clinical application*** of the information or course content through site visits; and
- Monitoring ***clinical outcomes*** of infants through data collection and analysis**.**

The objective of the first round study, conducted in 2001, was to determine the effectiveness of the NRP and was part of a larger quality improvement initiative, which included monitoring of courses and evaluation of clinical application of the guidelines. Specifically, the study was to determine if there was a positive impact on selected neonatal outcomes which could be directly attributed to the implementation of the NRP training.

The objective of the second round study, conducted in 2003, was to monitor clinical outcomes and assess the effectiveness of the NRP program in improving outcomes. The second round refined the monitoring process and contributed to the systematic use of data for the purpose of quality assurance. During the second round, the HFH partnership expanded its role in mentoring the NRTCs in analysis of data for quality assurance.

IV. METHODOLOGY

The methodology used for the two studies differed somewhat. The methodology and the limitations of the methodologies are described below. The main outcome measures were Apgar scores at 1 and 5 minutes of life; central nervous system (CNS) status at 1 hour and 7 days of life; the incidence of asphyxia, respiratory distress syndrome (RDS), and meconium aspiration syndrome (MAS); mortality related to asphyxia, RDS, and MAS; and overall survival in the first 7 days of life. The Apgar score is universally used as an indicator of a newborn's condition at time of birth and within the first few minutes of life. The Apgar score can also assist in the prediction of long-term neurological outcome of the infant.

Designated levels of hospitals are based on the Guidelines for Perinatal Care established by the American Academy of Pediatrics/American College of OB/GYNs. Level I institutions provide basic obstetrics and newborn care to low risk mothers and infants; often the institutions are small community or rural hospitals. Staff are able to resuscitate and stabilize infants but sick mothers and infants are transported to a Level III facility. Level II institutions are district hospitals that can provide for some obstetrics and neonatal disease processes; the hospitals generally have a neonatologist in house 24 hours a day. Level III institutions provide care to the sickest infants and mothers; a full range of diagnostic services, high risk obstetrical physicians, and neonatal intensive care services are available.

FIRST ROUND STUDY: INITIAL MONITORING OF CLINICAL OUTCOMES

The 16 AIHA NRTCs operating at the time were asked to participate in prospective data collection during July-November, 2001. Data from 3 NRTCs was excluded due to inaccuracies in collection and reporting. Data from 13 centers in these countries was used in the analysis:

- Ukraine (6)
- Russia (4)
- Azerbaijan (1)
- Georgia (1)
- Uzbekistan (1)

A data collection tool was developed to obtain standard information on all infants from birth to 7 days of life. Each center was asked to provide information on 625 consecutive births, with a target N = 10,000. Approximately 1 to 3 maternity hospitals within each region, where staff had been trained in NRP, participated in the study. The hospitals prospectively collected data on all infants who were born in their institutions who were > 28 weeks gestation and with birth weight > 1,000 grams. This included both infants requiring resuscitation and those not requiring resuscitation. Infant data was collected at birth and at seven days of life.

The NRTC Director provided individual instruction to the hospital data collector, most often the chief neonatologist of the maternity hospital. Once individual infant data collection was completed, the forms were returned to the NRTC and data was entered into an Excel spreadsheet. The centers then electronically submitted this data to the authors for analysis.

In addition to individual infant data, each NRTC collected basic demographic information about participating institutions that included: the level of care provided by the institution, the number of medical staff by professional categories, the number of staff trained in NRP in each profession, and the availability of essential resuscitation equipment.

A set of control group data where NRP had not yet been implemented was unavailable. No institution could be identified where NRP training had not been initiated. Therefore, data was stratified for analysis by percent of staff trained in neonatal resuscitation.

SECOND ROUND STUDY: MONITORING OF CLINICAL OUTCOMES

In 2003, a second round of monitoring was undertaken with the intention of replicating the data collection in the first round. As a result of feedback from the NRTC Directors, some modifications were made in the data collection process and tools for the second round. Strict definitions and diagnostic criteria for perinatal asphyxia, RDS, and MAS were proposed. The process and data collection tools are attached in Appendices 1-4.

Data was obtained from 16 NRTC and 64 hospitals over a two-month timeframe (May-June for some hospitals and June-July for others) in 2003. The total N = 8,386 infants. Distribution by birth is depicted in Table I, Appendix II. Data from Center # 7 (Moscow) was not included and data from Center # 4 (Kharkiv) and Center # 13 (Ulan-Ude) were partially removed (from separate hospitals) because of missing data about personnel trained in NRP. There were almost twice as many level II hospitals as level I hospitals, and one-third more level II than level III hospitals. The majority of births occurred in Level II and III hospitals.

METHODOLOGY LIMITATIONS

There are inherent limitations in the methodology and the two rounds of data collection. First, a pure control group before NRP training to compare with results after training could not be obtained. Secondly, the sample populations in the two data sets were not identical. This could not be controlled for since

consecutive births were recorded from each institution. Thirdly, the availability of basic equipment and supplies for neonatal resuscitation, e.g., ambu bags and masks, varies and is scarce in the NIS countries. The ability of even trained staff to implement basic principles is often limited by these shortages. Fourthly, definitions of RDS, MAS, and asphyxia are much more subjective without laboratory data to corroborate clinical findings. The lack of such diagnostic tools in the NIS brings into question the accuracy of the diagnoses and caution should be exercised when interpreting these findings due to subjectivity and error in diagnoses. Fifthly, the Apgar score continues to be used as an outcome measure because of its widespread acceptance, but it has both inter-rater and independent rater variability. In the study population, with a mixture of full-term and premature infants, a bias can be introduced because the use of the Apgar score is even more subjective in the premature infant. Finally, there are limitations due to subjectivity regarding timing of scores since many delivery rooms in the NIS do not have clocks, much less Apgar clocks.

V. FINDINGS

FIRST ROUND STUDY: INITIAL MONITORING OF CLINICAL OUTCOMES

The findings of the first round study were submitted in the form of a journal article to *Pediatrics* and to AIHA. After an intense peer review process, the data related to the Apgar scoring was rerun and the article was revised. This revised article is being submitted for publication to the *Journal of Perinatology*. The results of this study suggested that in institutions where NRP training has taken place, the incidence of significant morbidities in the immediate newborn period may be reduced even in countries where a severe shortage of equipment and supplies exists. Improvements in neonatal outcomes noted in the NIS countries, in the absence of other major clinical changes, appear to support the effectiveness of structured NRP training. The findings are subject to the limitations of using the Apgar score as the sole measure in determining effectiveness of NRP training due to its subjectivity in all infants and especially in premature infants.

A total of 8,292 births were included in the first round analysis. The critical percentage of staff trained was found to be 25% of staff at each institution and the births were grouped accordingly. The findings were that clinical outcomes for infants born in institutions where > 25% of the staff had been trained in NRP were better than for infants born in institutions where < 25% of the staff had been trained in NRP. These findings were valid for infants requiring resuscitation and infants not requiring resuscitation. Among the clinical outcomes examined, only the incidence of MAS did not vary significantly between the two groups of infants. The infants at institutions with >25% trained staff had better 5-minute Apgar scores; were more often intubated for suction of meconium in the amniotic fluid; had less CNS pathology at 7 days of life; had lower mortality at 7 days of life; had lower mortality from asphyxia and RDS; and had lower incidence of asphyxia and RDS. These differences in outcomes remained valid when case risk was controlled for by excluding data from level I hospitals in the analysis.

SECOND ROUND STUDY: MONITORING OF CLINICAL OUTCOMES

A profile of infants in the second round data set is shown in Table 2, Appendix II. There was a statistically significant difference in the mean birth weight as well as the mean gestational age between the two groups of infants. At the outset of data analysis, the groupings were kept as in the earlier study. Group I was defined as infants who were born in hospitals where $\leq$ 25% of staff were trained, and Group II was defined as infants born in hospitals where > than 25% of staff were trained. The differences in these groups were due to the method of collecting data which was consecutive births rather than randomized births (the authors of the study requested consecutive births because the option of randomizing and accepting data only on particular sized infants was no practical).

In the course of data analysis, the previous model of grouping infants, Group I and Group 2 as defined above, was found to no longer affect neonatal outcomes (Table 3, Appendix II). This model had been

based on training ALL medical personnel. This threshold did not affect infants' Apgar score distribution and neonatal morbidity and mortality; and increasing the numbers of trained staff did not produce any improvement of low Apgar scores. On the one hand, the most probable explanation is that NRP has been extensively implemented in most institutions in these regions. For example, in many regions in Ukraine the formal NRP training has been systemically implemented since 1997 (and in some institutions since 1994) and thousands of professionals have been involved in the process. This may contribute to the result that the lack of formal training no longer indicates an inability to effectively resuscitate a newborn in the hospitals situated within areas of program implementation. On the other hand, there are many factors apart from training which affect outcomes for infants. Although the NRP training is directed at all staff participating as a team in the resuscitation of an infant, it is the neonatologist in these NIS hospitals who attends and is responsible for resuscitation. The support staff may play a smaller role than originally believed.

The distribution of infants born with low one-minute Apgar scores (0-6) is shown in Table 4, Appendix II. There were more infants with a lower 1 minute Apgar score delivered at hospitals where all the neonatologists were trained in NRP and more than 25% of all staff was trained. This was also true when Level III hospitals were considered. This distribution reflects the clinical distribution of high-risk pregnancies, which are often delivered at level III hospitals.

The effect of trained personnel on newborns' distribution based on the 1- and 5-minute Apgar score is shown in Table 5. It is clear that there is improvement in all categories of Apgar scores between 1 and 5 minutes of life, suggesting training or intervention of staff results in fewer infants at 5 minutes with lower Apgar scores. The most significant clinical improvement can be seen in the group of infants requiring Positive Pressure Ventilation (PPV), where very few infants had an Apgar of 7–10 at 1 minute but there was a drastic increase of infants with this score at 5 minutes. For infants requiring PPV, statistical significance is achieved between the 1 and 5 minute score in all Apgar score groups, $p < 0.00001$.

In analyzing the improvement of Apgar scores between 1 and 5 minutes, in all Apgar score categories (0-3, 4-6, 7-10), the same observation applied when level of hospital was considered, regardless of trained staff being $\leq 25\%$ or $> 25\%$ of staff (Table 6). These differences were not sustained when $\leq 25\%$ training was compared with $> 25\%$ training in level I and level II hospitals. There were more infants with lower 1 minute Apgar scores in level III hospitals where $\leq 25\%$ of staff were trained as compared to the group where $> 25\%$ were trained ($p < 0.01$). Because the one minute Apgar score can be affected if intervention does not occur quickly and correctly, perhaps in institutions where less people were trained the start of resuscitation and the skill level of providers is less therefore the impact on assisting infants who need support in the first minute of life is not as great as it may be in institutions where more people were trained.

Tables 6A and 6B represent the general distribution of infants based on Apgar scores at 1 and 5 minutes. It is clear from these tables that this distribution is different between 1 and 5 minutes with a significant reduction of lower Apgar scores from 1 to 5 minutes and simultaneous increase in higher Apgar scores. This can be considered a normal tendency for infants in the first few minutes of life and is not necessarily dependent on training. These differences were not consistent, clinically significant, or conclusive.

In Table 6A, the effect of the percentage of trained neonatologists on the distribution of newborns by 1 and 5 minute Apgar scores depending on hospital level suggests the following: first, the hospital level does affect Apgar distribution; and secondly, data from the level II hospitals (where the most deliveries occurred) supports the suggestion that training of neonatologists does affect outcomes ($p < 0.00001$). Considering that there are fewer infants with significant medical conditions delivered in these hospitals, the infant's condition is not an additional complicating factor as it is in level III hospitals.

Where 100% of neonatologists were trained, there was a statistically significant improvement in the 1 minute Apgar score (all categories 0-3, 4-6, 7-10) by 5 minutes in hospitals of all levels, separately or combined (Table 6B). However, between the two groups, 100% of neonatologists trained and < 100% neonatologists trained, there was no statistically significant difference. This table represents resuscitated infants only, and there is no difference between the two groups within each hospital level. The difference between the 1 and 5 minute distribution does exist and is highly significant. But, this general difference does not necessarily mean that the condition of every infant with a low Apgar score at 1 minute really improved by 5 minutes. The study's intention was to compare the number of infants with such an improvement within every group and the results of this comparison are presented in Table 3A.

Tables 3A and 7A represent the differences between the groups based on the numbers and percentages of newborns who had a low (0-6) Apgar score at 1 minute and an increase in the Apgar score at 5 minutes ("simple" improvement, Table 3A) or increased the score by more than 1 point (Table 7A). The improvement depicted in Table 7A has more clinical significance as the score is improved by at least 1 point. The data shows that significantly more infants improved their scores in the hospitals where 100% of neonatologists were trained and again this effect was most pronounced in Level II hospitals, both for the "simple" and "significant" improvement in Apgar score (Table 3A).

In hospitals where 100% of neonatologists were trained in NRP there was clear improvement in the 5 minute Apgar score when the 1 minute Apgar score was low (Table 7A). This was a clear trend in all levels of hospitals but reached statistical significance when all hospitals were combined and in Level II hospitals individually. This is due to the high number of births in the level II hospitals.

The distribution of infants based on percent of neonatologists trained is seen in Table 7B. Once again, the number of infants needing resuscitation was not different. However, the two groups of infants were different in birth weight, gestational age, and level of hospital.

There was a reduction in neonatal morbidities and mortalities in many categories when comparing 100% of neonatologists trained with < 100% neonatologists trained. Table 8 shows a statistically lower incidence of RDS ($p < 0.01$), MAS ($p < 0.000001$), death due to perinatal asphyxia ($p < 0.001$), death due to RDS ($p < 0.0001$), and death due to MAS ($p < 0.00001$) in hospitals where 100% of neonatologists were trained; this holds true even when low birth weight and short gestational are taken into account. Birth weight and gestational age were controlled for in logistic regression analysis. Although one can see a smaller proportion of cases with CNS abnormalities at 1 week and death at 1 and 7 days, in the same group, those differences were not statistically or clinically significant.

To confirm the independent effect of NRP training on neonatal outcomes, which were more favorable in hospitals with 100% trained neonatologists based on univariable analysis, logistic regression analysis was conducted to control the influence of gestational age, hospital level, and severity of the infant's condition (1 minute Apgar score). Based on the results of this analysis (Table 9), infants born in the hospitals where 100% of the neonatologists were trained in NRP had significantly more chances of Apgar improvement with less morbidity in RDS and MAS, and less mortality due to perinatal asphyxia, RDS and MAS independently of their gestational age, Apgar score at 1 minute, or hospital level.

VI. CONCLUSIONS

The purpose of the analysis of clinical outcome monitoring was to evaluate the clinical effectiveness of implementing NRP. The results of the two studies, which included data on more than 15,000 infants in many hospitals throughout the NIS, were consistent and supported the positive effect of organized NRP training on morbidity and mortality of newborns. In 2001, the first study found the distribution of hospitals based on the percentage of total medical personnel trained in NRP made the greatest impact on

neonatal outcomes. In hospitals where more than 25% of staff was trained, newborns had significantly more chances of improving their low 1 minute Apgar scores and less chance of developing perinatal asphyxia, RDS, die by the 7th day of life, or die from asphyxia and RDS.

In 2003, the situation was different and neonatal outcomes were no longer affected by hospital distribution based on percentage of total medical personnel trained. Neonatal resuscitation knowledge and skills were widespread at this stage. The study examined the training of the pivotal persons in charge of resuscitation of newborns, neonatologists, and found an effect which was not present in the first round of data analysis. Infants born in hospitals where all neonatologists (100%) were trained in NRP had significantly more chances of Apgar score improvement with less morbidity, less RDS and MAS, and less mortality due to perinatal asphyxia, RDS, and MAS independently of their gestational age, Apgar score at 1 minute or hospital level. This supports the contention that having all neonatologists trained in NRP in current circumstances in the NIS is the most important factor in improving early neonatal outcomes.

Both rounds of data analysis have some methodological limitations, mainly the lack of a pure control group, which is nearly impossible to obtain due to the many education and training efforts underway in the NIS. Despite this and other limitations, the data appears to support a positive effect of formal NRP training on neonatal outcomes. The results of this data analysis continue to support the effectiveness of the model of Regional Neonatal Resuscitation Training Centers developed, implemented, and supported by AIHA through funding by USAID.

Appendix I

I.1 Data Collection Procedure – Second Round

American International Health Alliance (AIHA)
Neonatal Resuscitation Program (NRP)
Data Collection Procedure – Second Round

Objective: To determine the impact over time of the Neonatal Resuscitation Program (NRP) Training.

1. Each AIHA NRP Training Center (NRP TC) (N=17) will participate in the collection of data.
2. Each NRP TC will be asked to contribute data on ~ 650 births prospectively.
3. All hospitals participating will collect data prospectively, for a defined time period, _____(***month and year. Eg May 2003, This date is yet to be determined.)***
4. Data on **all births** at this institution will be collected. Only infants ≥ 28 weeks or ≥ 1000gms should be included.

Responsibilities of the NRP Training Center:

1. To enlist Primary Maternity Hospitals in their Region, where neonatal resuscitation training has occurred, to participate in this data collection. These institutions may be of varying sizes. The number of institutions participating in a Region will depend on the number of deliveries per month in the institutions selected.
2. To complete the Hospital Profile form for each institution selected to participate.
3. To determine with the Maternity Hospital staff the person(s) who will be responsible for collection of the data.
4. To print the Individual Data Forms locally.
5. To train the data collectors in the use of the data collection tool and then practice filling out the form with the data collector (s), i.e. it may be helpful to assist them in completing ~ 5 forms.
6. To receive data collected on each birth in selected Maternity hospitals and to compile the data on an excel spreadsheet (format attached).
7. To send the data electronically on excel spreadsheet to Sudhakar Ezhuthachan, MD, NRP Steering Committee data group leader. (sezhuth1@hfhs.org)
8. All data will be due _____ ***(one month from the end of the month which has been chosen for collection.)***.

Responsibilities of the Maternity Hospital:

1. To determine with the NRP TC staff that is best qualified to collect the data.
2. Data collectors chosen will participate in the training of data collection with the NRP TC staff and complete some sample forms.
3. To collect data on all births for the Month of _____ 2003. Only infants ≥ 28 weeks gestations or ≥ 1000 grams should be included.
9. To send all individual data sheets to the NRP Training Center.

NOTE: The AIHA Regional staff will help centers with the excel format and other concerns as needed. Sudhakar Ezhuthachan, MD, Chris Newman, CNNP and Dmytro Dobrianskyy, MD are also available to assist with questions and concerns.

Documents for the process include:

1. Data Collection Process
2. Individual data collection sheet and instructions
3. Hospital Profile Form
4. Excel Spreadsheet

Appendix I
I.2 Instructions for Individual Data Collection Forms

Introduction: As part of continued efforts to improve the care to newborns, the Neonatal Resuscitation Program (NRP) was implemented throughout the NIS with funding and support from AIHA and USAID. In an effort to evaluate the clinical effectiveness of this course we are requesting selected institutions to participate in data collection. The outcome of the data will be used to gain continued support for this effort and will also be shared with all participating institutions. We appreciate your efforts to assist us in this process.

1. *Please complete the Individual Data Collection Form on **each** infant born in your institution at ≥ 28 weeks gestation or ≥ 1000 grams during the month of _____ 2003.*

2. *Most items require only a check (√) or simple numbers. If the infant required intubations, please indicate the reason for intubations.*

3. *Once all forms are completed, they should be sent to the NRP TC.*

4. *All questions should be directed to _____, at _____ (contact at NRP TC should be completed here).*

We thank you for your assistance in this effort!

Appendix I
I.3 Clinical Outcome Evaluation

Hospital Name:
Infant Name: **Identification number:**
Date of Birth:

Birth weight: grams	**Gestational Age:** weeks
Apgar Score: @1 minute, @5 minute	
Resuscitation (Check all that was required):	
Oxygen (blow by): yes ____ no_____	**Chest Compressions: yes____ no____**
Positive Pressure ventilation: yes ___ For how long _____ no_____	
Medication: Epinephrine: yes ___ no____ Volume: yes ___ no ___ Bicarbonate: yes ____ no ___	**Intubation: yes ___ no_____** Reason:
Temperature: First temperature _____ Age of infant in minutes _____ **Method:** axillary ___ rectal ___ Taken in delivery room _____nursery_____	
If temperature taken in the Delivery room , Temperature at time of transfer to nursery _____	
Outcomes:	
At 1 hour of age: Normal * yes ___ no____ CNS Abnormality** yes ___ no___ (severe hypotonia, seizures, coma) Death yes___ no___	
Infant is discharged < 7 days of age: yes___ no___ (Assume outcome is normal at the age of 7 days)	
At 7 days of life: : Normal: yes___ no___ CNS Abnormality yes___ no___ (severe hypotonia/hypertonia, atonia, term infant with no suck/swallow, seizures, coma) Death: yes ___ no____ Age of Death_____(days) Cause of death (autopsy): Asphyxia: yes___ no___ RDS: yes ___ no___ Aspiration Syndrome: yes ____ no____ Birth Trauma: yes ____ no____ Perinatal Infection: yes ___ no____ Other:_____	
Infant Transferred to another institution: Age at transfer: _____(hours, days) Reason for transfer: _____	
Morbidities:	
Asphyxia: yes ___ no___	Respiratory Distress Syndrome: yes___ no____
Meconium Aspiration Syndrome: Yes ___ no___	
Comments:	

* - normal means the lack of indicated CNS abnormalities
** - only indicated signs should be taken into account.
NOTE: Please complete every item. Please complete yes or no when indicated.

Appendix I
I.4 Individual Hospital Profile

This form is to be completed by the staff of the NRP Training Center for each hospital selected to participate in data collection.

Hospital Name:_____
City: _____
Region:_____ **Country:_____**

Date NRP first taught to staff in this hospital:_____
Date of last NRP training to any staff at this hospital:_____

# of people trained by category / # of staff in this institution by category

Neonatologists____/____ Obstetricians____/____

Pediatricians ____/____ Anesthesiologists____/____

Nurses ____/____ Midwives ____/____

Number of births in year 2002_____

Resuscitation equipment available to this staff in their delivery room:

Oxygen supply: Central ____ Portable ____ None ____

Bag and masks for ventilation: yes ____ no _____
If yes,
Number of Bags ____ Masks ____

Laryngoscope Blades: yes ____ no ____
If yes,
Number of # 0 ____ # 1 ____

Laryngoscope handles: yes ____ no ____
If yes,
Number of handles_____

Suction source: yes ____ no ____

Neonatology coverage:
____no neonatology coverage
____staff neonatologist is available
____24 hour coverage with neonatologist in hospital

University hospital: yes ____ no ____
Specializes in Preterm deliveries/maternal pathology: yes ___ no ___
NICU in hospital: yes ____ no ____
:/outcome data

Appendix II

ANALYSIS OF THE SECOND ROUND OF NRP DATA

Year 2003

n = 8386 from 16 NRP centers & 64 hospitals

Table 1 - Distribution of Births by NRP Training Center

Center Number	Number of Births	Number of Hospitals			Births by Hospi	
		Level I	*Level II*	*Level III*	*Level I*	*Level II*
1	770	2	6	0	23	747
2	599	1	3	0	149	450
3	603	2	2	2	76	284
4	118	1	1	0	50	68
5	601	0	7	0	0	601
6	600	1	1	1	123	200
8	600	0	1	2	0	209
9	614	4	3	0	278	336
10	218	0	0	1	0	0
11	708	0	2	1	0	503
12	584	0	3	5	0	128
13	591	0	0	2	0	0
14	556	0	0	3	0	0
15	599	0	2	1	0	356
16	625	3	0	1	161	0
Total	**8386**	**14**	**31**	**19**	**860**	**3882**

Data from Center #7 (Moscow) not included and data from Center #4 (Kharkiv) and Center #13 (Ulan-Ude) were taken out partially (from separate hospitals) because missing data about personnel trained in NRP.

Table 2 - Profile of infants

Indicator	Group I - Hospitals with ≤25% staff trained *(n=1711)*	Group II - Hospitals >25% staff traine *(n=6675)*
Number of resuscitated infants* (%)	149 (8.7)	515 (7.7)
Birth weight, g‡	3220.97 ± 572.81	3285.45 ± 550.47
Gestational age, wks‡	38.71 ± 2.03	38.81 ± 1.77
Number of infants depending on birth weight category		
1000–1499 g (%)	26 (1.52)	48 (0.72)
1500–1999 g (%)	34 (1.99)	104 (1.56)
2000–2499 g (%)	72 (4.21)	327 (4.9)
≥2500 g (%)	1579 (92.29)	6196 (92.82)
Number of infants depending on gestational age category		
< 33 wks (%)	40 (2.34)	100 (1.5)
33-37 wks (%)	178 (10.4)	733 (10.98)
> 37 wks (%)	1493 (87.26)	5842 (87.52)
Number of infants born in different level hospitals		
Level I hospitals (%)	23 (1.34)	837 (2.34)
Level II hospitals (%)	499 (29.16)	3383 (50.68)
Level III hospitals (%)	1189 (69.49)	2455 (36.78)

***** Defined as at least a need for positive pressure ventilation (PPV).

† NS – not significant ($p > 0.05$).

‡ Mean ± SD.

Table 3 - Changes between 1-minute and 5-minute Apgar scores in high-risk newborns with a low 1-minute Apgar (0-6) by hospital level depending on percentage of staff trained in neonatal resuscitation*

Hospital level	Indicator	Hospitals with ≤ 25% staff trained	Hospitals with > 25% staff trained
1	No Apgar improvement at 5 min	0	1 (1.39)
	Apgar improvement at 5 min†	3 (100)	71 (98.61)
	Total for level I hospitals	*3*	*72*
I1	No Apgar improvement at 5 min	1 (1.37)	25 (5.49)
	Apgar improvement at 5 min†	72 (98.63)	430 (94.51)
	Total for level II hospitals	*73*	*455*
I1I	No Apgar improvement at 5 min	6 (2.7)	21 (3.74)
	Apgar improvement at 5 min†	216 (97.3)	541 (87.9)
	Total for level III hospitals	*222*	*562*
All hospitals	No Apgar improvement at 5 min	7 (2.35%)	47 (4.32)
	Apgar improvement at 5 min†	291 (97.65%)	1042 (95.68)
	Total	**298**	**1089**

* The numbers of infants with percentages in parenthesis are presented.

† Increasing of 1-minute score at least by 1 point.

‡ NS – not significant ($p > 0.05$).

Table 4 – Distribution of high-risk newborns with a low 1-minute Apgar (0-6) depending on percentage of staff trained in neonatal resuscitation in level III hospitals b

Training in NR of Neonatologists in Level III hospitals	Hospitals with ≤25% staff trained	Hospitals with >25% staff trained
<100% neonatologists trained in NR	89 (40.1%)	34 (6.1%)
100% neonatologists trained in NR	133 (59.91%)	528 (93.95%)
Total for level III hospitals	*222*	*562*

Table 5 - Effect of percent of trained personnel on newborns' distribution based on 1- and 5-minute Apgar scores*

Apgar scores		All infants			Infants requ	
		≤ 25% of the staff trained *(n=1711)*	**> 25% of the staff trained** *(n=6675)*	***P value*** ≤25% vs >25%	**≤ 25% of the staff trained** *(n=149)*	**> 25% of staff train** *(n=515)*
0-3	1 min	38 (2.22)	104 (1.56)		28 (18.79)	96 (18.6
	5 min	6 (0.35)	27 (0.4)		5 (3.36)	27 (5.24
4-6	1 min	260 (15.2)	985 (14.76)	*NS*	115 (77.18)	387 (75.1
	5 min	86 (5.03)	274 (4.1)		53 (35.57)	216 (41.9
7-10	1 min	1413 (82.58)	5586 (83.69)		6 (4.03)	32 (6.21
	5 min	1619 (94.62)	6374 (95.49)		91 (61.07)	272 (52.8
P *1-5 min*		*< 0.00001*	*< 0.00001*		*<0.00001*	*<0.0000*

* Presented the numbers of infants with percentages in parenthesis; NS – not significant (p > 0.05).

Table 6 - Effect of percent of trained personnel on newborns' distribution by 1- and 5-minute Apgar scores depending on hospital level

Apgar scores		Level I			Level II			
		≤25% of staff trained *(n=23)*	>25% of staff trained *(n=837)*	***P value*** ≤ 25 % vs > 25 %	≤25% of staff trained *(n=499)*	>25% of staff trained *(n=3383)*	***P value*** ≤ 25 % vs > 25 %	≤25% of staff trained *(n=1189)*
		Number of infants (percent in each category)						
0-3	1 min	0 (0)	7 (0.84)		9 (1.8)	47 (1.39)		29 (2.44)
	5 min	0 (0)	2 (0.24)		2 (0.4)	14 (0.41)		4 (0.34)
4-6	1 min	3 (13.04)	65 (7.77)	*NS*	64 (12.83)	408 (12.06)	*NS*	193 (16.23)
	5 min	0 (3.01)	6 (0.72)		9 (1.8)	105 (3.1)		77 (6.48)
7-10	1 min	20 (86.96)	765 (91.4)		426 (85.37)	2928 (86.55)		967 (81.33)
	5 min	23 (100)	829 (99.04)		488 (97.8)	3264 (96.48)		1108 (93.19)
P *1-5 min*		*<0.000001*	*<0.000001*		*< 0.00001*	*< 0.00001*		*< 0.000001*

***** NS – not significant ($p > 0.05$).

Table 7 – Clinically significant changes between 1-minute and 5-minute Apgar scores in high-risk newborns with a low 1-minute Apgar (0-6) by hospital level depending on percentage of staff trained in neonatal resuscitation

Hospital level	Indicator	Hospitals with ≤25% staff trained	Hospitals with >25% staff trained
All hospitals	No clinically significant Apgar improvement at 5 min	160 (53.69%)	670 (61.52%)
	Apgar improvement at 5 min†	138 (46.31%)	419 (38.48%)
	Total for all hospitals	*298*	*1089*
1	No clinically significant Apgar improvement at 5 min	1 (33.33%)	18 (25%)
	Apgar improvement at 5 min†	2 (66.67%)	54 (75%)
	Total for level I hospitals	*3*	*72*
I1	No clinically significant Apgar improvement at 5 min	38 (52.05%)	304 (66.81%)
	Apgar improvement at 5 min†	35 (47.95%)	151 (33.15%)
	Total for level II hospitals	*73*	*455*
I1I	No clinically significant Apgar improvement at 5 min	121 (54.5%)	348 (61.92%)
	Apgar improvement at 5 min†	101 (45.5%)	214 (38.08%)
	Total for level III hospitals	*222*	*562*

***** NS – not significant ($p > 0.05$);

† Increase of the score at 1 min (0-6) by more than 1 point.

The main conclusion from the data presented above is that the infant distribution based on the > or < than 25% of ALL medical staff trained in NR no longer affects neonatal outcomes.

Table 7A – Clinically significant changes between 1-minute and 5-minute Apgar scores in high-risk newborns with a low one-minute Apgar (0-6) by hospital level depending on percentage of <u>neonatologists</u> trained in neonatal resuscitation

Hospital level	Indicator	Hospitals with <100% neonatologists trained	Hospitals with 100% neonatologists trained	
All hospitals	No clinically significant Apgar improvement at 5 min	268 (64.89%)	562 (57.7%)	
	Apgar improvement at 5 min†	145 (35.11%)	412 (42.3%)	
	Total for all hospitals	*413*	*974*	
1	No clinically significant Apgar improvement at 5 min	9 (31.03%)	10 (21.74%)	
	Apgar improvement at 5 min†	20 (68.97%)	36 (78.26%)	
	Total for level I hospitals	*29*	*46*	
I1	No clinically significant Apgar improvement at 5 min	181 (69.35%)	161 (60.3%)	
	Apgar improvement at 5 min†	80 (30.65%)	106 (39.7%)	
	Total for level II hospitals	*261*	*267*	
I1I	No clinically significant Apgar improvement at 5 min	78 (63.41%)	391 (59.15%)	
	Apgar improvement at 5 min†	45 (36.59%)	270 (40.85%)	
	Total for level III hospitals	*123*	*661*	

***** NS – not significant ($p > 0.05$);
† Increase of the score at 1 min (0-6) by more than 1 point.

Table 3A - Changes between 1-minute and 5-minute Apgar scores in high-risk newborns with a low 1-minute Apgar (0-6) by hospital level depending on percentage of neonatologists trained in neonatal resuscitation*

Hospital level	Indicator	Hospitals with <100% neonatologists trained	Hospitals with 100% neonatologists trained
1	No Apgar improvement at 5 min	0	1 (2.17)
	Apgar improvement at 5 min†	29 (100)	45 (97.83)
	Total for level I hospitals	*29*	*46*
I1	No Apgar improvement at 5 min	20 (7.66)	6 (2.25)
	Apgar improvement at 5 min†	241 (92.34)	261 (97.75)
	Total for level II hospitals	*261*	*267*
I1I	No Apgar improvement at 5 min	5 (4.07)	22 (3.33)
	Apgar improvement at 5 min†	118 (95.93)	639 (96.67)
	Total for level III hospitals	*123*	*661*
All hospitals	No Apgar improvement at 5 min	25 (6.05%)	29 (2.98)
	Apgar improvement at 5 min†	388 (93.95%)	945 (97.02)
	Total	**413**	**974**

* The numbers of infants with percentages in parenthesis are presented.
† Increasing of 1-minute score at least by 1 point.
‡ NS – not significant ($p > 0.05$).

Table 7B - Profile of infants based on distribution by percentage of <u>neonatologists</u> trained in neonatal resuscitation

Indicator	Group A - Hospitals with <100% neonatologists trained *(n=2966)*	Group B - Hospit 100% neonatologis *(n=5420)*
Number of resuscitated infants* (%)	220 (7.42)	444 (8.19)
Birth weight, g‡	3240.14 ± 551.85	3293.78 ± 55
Gestational age, wks‡	38.62 ± 1.93	38.88 ± 1.7
Number of infants depending on birth weight category		
1000–1499 g (%)	40 (1.35)	34 (0.63
1500–1999 g (%)	45 (1.52)	93 (1.72)
2000–2499 g (%)	131 (4.42)	268 (4.94)
≥2500 g (%)	2750 (92.72)	5025 (92.7
Number of infants depending on gestational age category		
< 33 wks (%)	55 (1.85)	85 (1.57
33-37 wks (%)	377 (12.71)	534 (9.85)
> 37 wks (%)	2534 (85.43)	4801 (88.5
Number of infants born in different level hospitals		
Level I hospitals (%)	333 (11.23)	527 (9.72)
Level II hospitals (%)	1399 (47.17)	2483 (45.8
Level III hospitals (%)	1234 (41.6)	2410 (44.4

***** Defined as at least a need for positive pressure ventilation (PPV).

† NS – not significant ($p > 0.05$).

‡ Mean ± SD.

Table 6A - Effect of percentage of trained neonatologists on distribution of newborns by 1- and 5-minute Apgar scores depending on hospital level (*all infants*)*

Apgar scores		All hospitals			Level I			Level II			
		Group A† *(n=2966)*	Group B† *(n=5420)*	***P value***	Group A *(n=333)*	Group B *(n=527)*	***P value***	Group A *(n=1399)*	Group B *(n=2483)*	***P value***	C *(n*
		Number of infants (percent in each category)									
0-3	1 min	56 (1.89)	86 (1.59)	*<0.00001 (1 min) NS (5 min)*	3 (0.9)	4 (0.76)	*NS*	30 (2.14)	26 (1.05)	*<0.00001*	
	5 min	17 (0.57)	16 (0.3)		1 (0.3)	1 (0.19)		11 (0.79)	5 (0.2)		
4-6	1 min	357 (12.04)	888 (16.38)		26 (7.81)	42 (7.97)		231 (16.51)	241 (9.71)		
	5 min	119 (4.01)	241 (4.45)		3 (0.9)	3 (0.57)		64 (4.57)	50 (2.01)		
7-10	1 min	2553 (86.08)	4446 (82.03)		304 (91.29)	481 (91.27)		1138 (81.34)	2216 (89.25)		((
	5 min	2830 (95.41)	829 (95.26)		329 (98.8)	523 (99.24)		1324 (94.64)	2428 (97.78)		((
P *1-5 min*		*<0.00001*	*<0.00001*		*< 0.0001*	*< 0.0001*		*< 0.0001*	*< 0.0001*		<

* The numbers of infants with percentages in parenthesis are presented.

† Group A - hospitals with <100% neonatologists trained; group B - hospitals with 100% neonatologists trained.

‡ **NS – not significant (p > 0.05).**

Table 6B - Effect of percentage of trained neonatologists on newborns' distribution by 1- and 5-minute Apgar scores depending on hospital level (*only resuscitated infants*)*

Apgar scores		All hospitals			Level I			Level II			
		Group A† *(n=220)*	Group B† *(n=444)*	***P value***	Group A *(n=24)*	Group B *(n=24)*	***P value***	Group A *(n=125)*	Group B *(n=118)*	***P value***	C
		Number of infants (percent in each category)									
0-3	1 min	47 (21.36)	77 (17.34)	*<0.00001 (1 min)*	3 (12.5)	3 (12.5)	*NS*	29 (23.2)	23 (19.49)	*NS*	
	5 min	16 (7.27)	16 (3.6)		1 (4.17)	1 (4.17)		11 (8.8)	5 (4.24)		
4-6	1 min	147 (66.82)	355 (79.95)	*NS (5 min)*	16 (66.67)	20 (83.33)		78 (62.4)	88 (74.58)		
	5 min	85 (38.64)	184 (41.44)		3 (12.5)	2 (8.33)		45 (36)	34 (28.81)		
7-10	1 min	26 (11.82)	12 (2.7)		5 (20.83)	1 (4.17)		18 (14.4)	7 (5.93)		
	5 min	119 (54.09)	244 (54.95)		20 (83.33)	21 (87.5)		69 (55.2)	79 (66.95)		
P *1-5 min*		*<0.00001*	*<0.00001*		*< 0.0001*	*< 0.0001*		*< 0.0001*	*< 0.0001*		

* The numbers of infants with percentages in parenthesis are presented.

† Group A - hospitals with <100% neonatologists trained; group B - hospitals with 100% neonatologists trained.

‡ NS – not significant ($p > 0.05$).

Table 8 - Neonatal Morbidities and Mortality

Indicator	**Group A -** Hospitals with <100% of neonatologists trained	**Group B -** Hospitals with 100% of neonatologists traine
Perinatal asphyxia	174 (5.87%)	289 (5.33%)
Respiratory distress syndrome (RDS)	82 (2.76%)	95 (1.75%)
Meconium aspiration syndrome (MAS)	35 (1.18%)	12 (0.22%)
CNS abnormality at 7 days	117 (3.97%)	173 (3.22%)
Death within 1 hour after birth	12 (0.4%)	13 (0.24%)
Death within 7 days after birth	13 (0.44%)	23 (0.42%)
Death due to perinatal asphyxia	50 (1.69%)	45 (0.83%)
Death due to RDS	28 (0.94%)	14 (0.26%)
Death due to MAS	18 (0.61%)	2 (0.04%)

Table 9 – Adjusted Odds Ratios (OR)* for Factors Affecting Neonatal Morbidities and Mortality

Dependent variables	Independent variables					
	100% of neonatologists trained in NR (0/1)	Gestational age of < 33 wks†	Gestational age of 33-37 wks†	1 min Apgar 0-3‡	1 min Apgar 4-6‡	h
Any Apgar score improvement**	1.29 (1.16-1.42) p<0.00001	0.79 (0.54-1.19) NS	0.87 (0.69-1.08) NS	2.67 (1.51-4.73) p<0.00001	2.53 (1.81-3.55) p<0.001	(1
Clinically significant Apgar score improvement††	1.62 (1.32-1.99) p<0.00001	0.93 (0.69-1.24) NS	0.79 (0.64-0.97) p<0.05	9.31 (7.085-12.24) p<0.00001	1.68 (1.43-1.97) p<0.00001	(2 p
Respiratory distress syndrome (RDS)	0.62 (0.43-0.9) p<0.05	6.88 (5.088-9.3) p<0.00001	1.32 (1.034-1.68) p<0.05	4.34 (3.029-6.22) p<0.00001	1.43 (1.11-1.85) p<0.01	(1 p
Meconium aspiration syndrome (MAS)	0.23 (0.12-0.47) p<0.00001	1.09 (0.55-2.17) NS	1.05 (0.61-1.79) NS	8.44 (4.96-14.39) p<0.00001	1.8 (1.17-2.76) p<0.01	(0
Death due to Asphyxia	0.63 (0.4-0.98) p<0.05	1.89 (1.23-2.92) p<0.01	1.17 (0.83-1.64) NS	5.96 (4.05-8.78) p<0.00001	1.52 (1.14-2.043) p<0.01	(0
Death due to RDS	0.34 (0.17-0.66) p<0.05	4.67 (2.69-8.1) p<0.00001	0.67 (0.39-1.15) NS	4.08 (2.34-7.13) p<0.00001	1.16 (0.75-1.81) NS	(0.
Death due to MAS	0.072 (0.016-0.32) p<0.001	1.45 (0.54-3.92) NS	0.69 (0.28-1.69) NS	5.62 (2.48-12.72) p<0.00001	1.74 (0.94-3.22) NS	(0

* 95% CI for OR in parenthesis.

† Gestational age was used as a categorical variable (1 - < 33 wks, 2 – 33-37 wks, 3 - >37 wks).

‡ 1 min Apgar scores were used in analysis as a categorical variable (1 – score 0-3; 2 – score 4-6; and 3 – score 7-10).

** Increase of the low score at 1 min (0-6) by at least 1 point.

†† Increase of the low score at 1 min (0-6) by more than 1 point.