

Project title

Effectiveness trial of day-care (DCA) versus usual care management of severe pneumonia with or without malnutrition in children using the existing health system of Bangladesh

(Phase I: January 2015 to December 2017; Expansion phase II – EAGLE supported: 1.7.2017 to 31.12.2019/2020; Start of patient enrolment in new study sites: 1.11.2017)

Project report V to EAGLE Foundation, period 1.1.2020 till 30.06.2020

Date: 31.05.2020- **Final report**

Place of performance

07 study sites in Dhaka city and rural areas northwest and northeast of Dhaka and Centre for Health and Population Research (icddr), Dhaka, Bangladesh in cooperation with University of Basel, Switzerland and the University of Kentucky, Lexington USA.

Investigators

Nur H Alam, Abu SG Faruque, Jubayer Chisti, Shahjahan Ali, Shah Nawaz Ahmed, Marufa Sultana, Tahmeed Ahmed, George Fuchs, Trevor Duke, Niklaus Gyr

Project brief

Principal Investigator	Dr. Nur Haque Alam, icddr Email: nhalam@icddr.org
Original project duration	January 2015 to January 2019 Extended until December 31st 2020
Donor	UNICEF Switzerland, Botnar Foundation & UBS Optimus Foundation, Switzerland, EAGLE Foundation Switzerland
Implementing Partners	icddr, MoHFW, UNICEF, Pathfinder, PSTC and CWFD
Implementation Location- 7 sites	Urban – Tikatuli, Circular road and Dhalpur Rural – Dhamrai, Karimganj, Pakundia, and Kishoregonj Sadar
Original Target (stat. power 0.85)	3500 children to be treated for severe pneumonia using either Daycare approach and referral system or existing management.
Modified Target (stat. power 0.80)	3000 children
Achievement per March 18th 2019	3226 children with severe pneumonia have been enrolled (intervention + control) for treatment under this study protocol STOP of enrolment-target number achieved/ end of field study
The budget of the expansion phase	USD 1 856 282, not including USD 136 815 for the 2 international cooperators and experts G.Fuchs USA and N.Gyr Basel, now partly supported by EAGLE and UNICEF special grant Dissemination credit of CHF 142 000 from UBSOF in 2019

EAGLE Foundation Grant

USD 25 414 for travel, administrative and office expenses of Prof. N.Gyr (no honorarium)

Background of the project

Successful management of children with severe pneumonia (WHO 2013) requires hospitalisation for antibiotic and supportive treatment such as pulse oximetry, oxygen therapy, nebulisation, nasopharyngeal clearance and monitoring etc. Most, if not all, developing countries including Bangladesh, do not have enough paediatric hospital beds

to accommodate the demand for admission of all children with severe pneumonia with or without malnutrition and other co-morbidities. It is therefore important to provide some other form of institutional care for those children suffering from severe pneumonia and malnutrition, which cannot be hospitalized but are too sick to be managed in the community.

The project team developed an **innovative and unique model** of Day Care Approach (DCA) as a safe and less expensive alternative to hospital management of severe childhood pneumonia and malnutrition. The new management approach has proven to be efficacious and cost-efficient (>33% less expensive) in several efficacy studies in urban Mirpur, Dhaka, under optimal test conditions (EAGLE study Pediatrics 2010)

Purpose of the study

The present trial aims to prove the safety, efficacy and effectiveness of DCA within the Bangladeshi health system in a large effectiveness trial- on a quasi strategic level

Study design and study locations

The project has been designed as a cluster-randomised controlled trial involving Primary Health Care Facilities in urban and rural areas under the health system of Bangladesh. The locations are:

Urban location (Wards)	Rural location (Unions)
Intervention and Day Care Clinic	
Tikatuli , Dayaganj, Wari, Jatrabari, Bashabo, Dhalpur , Shantinagar and Circular Road involving the Surjer Hashi Clinics	Dhamrai - Kushura, Sanora, Shombhag, Kulla Karimganj - Baroghoria, Joyka, Niamatpur, Gundhor Pakundia – Patuabhanga, Hosendi, Narandi, Sukhia Kishorgonj Sadar –Baulai, Jasodal, Danaptali, Maijkhpan involving the Health and Family welfare Clinics (HFWCs) under the Ministry of MoHFW
Control clinics (existing treatment protocol)	
Gandaria, Begumganj, Muradpur, Lalbagh, Aftabnagar, Maniknagar, Taltola and Badda involving the Surjer Hashi Clinics .	Balia, Jadabpur , Baishakanda , Nannar, Jafrabad, Kadirjongal , Noabad , Dahunda Jangalia, Barudia, Egarasindur, Charfaradi Binnati, Maria, Koshakariail, Chauddasata involving HFWCs under the MoHFW

Case Management of Pneumonia

- Children with pneumonia with/without malnutrition will be identified for treatment or those who are self-referred will receive therapy at home with an oral antibiotic for 5 days.
- Those children with pneumonia (i.e., not severe pneumonia) who will fail after two days of oral antibiotic therapy will be referred to hospital/DCA treatment if they fulfil the criteria of **severe** pneumonia.
- Children with **severe** pneumonia are referred directly to the hospitals/Daycare clinics.

How Daycare management works

Day Care treatment facility is a modified outpatient clinic with facilities similar to a hospital and equipped with trained physicians and nurses, 2-3 pediatric beds, availability of oxygen therapy with pulse oxymetry for measurement of oxygen saturation, long-acting injectable antibiotics, nasopharyngeal suction, nebulisation facilities and calorie dense diet for the children. The facility operates daily during office hours from 8:30 AM to ~4 PM. Children stay during this period. If not stabilised within this period, then the children are referred to the referral hospitals. Cell phone networking is maintained during night hours to guide or refer children to appropriate facilities. There is a regular follow up.

Study activities 1st half 2020 and situation of the trial per June 2020

As mentioned in the previous report IV, UBSOF agreed in December 2019 to further contribute USD 142 thousand for the completion of the study including diffusion and publication activities. We then requested UBSOF and EAGLE Foundation to grant a no cost extension till December 2020 which has kindly been approved by both agencies.

During the first half of 2020, we have completed the primary and advanced data analysis and drafted the final scientific report to be shared with donors, sponsors, external investigators and other stakeholders. It was originally intended to finalize the review and edit of the final scientific report by May 2020 and manuscript submissions were planned latest by midyear/end 2020. Due to the unforeseen COVID-19 crisis which endangers the already delicate Bangladeshi health care system the timetable had to be adapted as the icddr and UNICEF Dhaka research team is being employed in the defense activities against the Corona virus. Publications will therefore need additional time and hopefully will be submitted by end of this year. A further no cost extension is not envisaged at this moment.

Four areas of the trial qualify to be published:

1. Effectiveness Trial of Day-care versus Usual care Management of Severe Pneumonia with or without Malnutrition in Children using the Existing Health System of Bangladesh

Already drafted: Study report December 1st 2019- Clinical results
Submission: 0.

2. Household economic burden of childhood severe pneumonia in Bangladesh:
A cost-of-illness study

Authors: Dr. Marufa Sultana et al
Submission: PEDIATRICS/2020/000414 on 05/03/2020

3. Incidence, case fatality, mortality, and health care-seeking behavior of children with severe pneumonia in rural Bangladesh

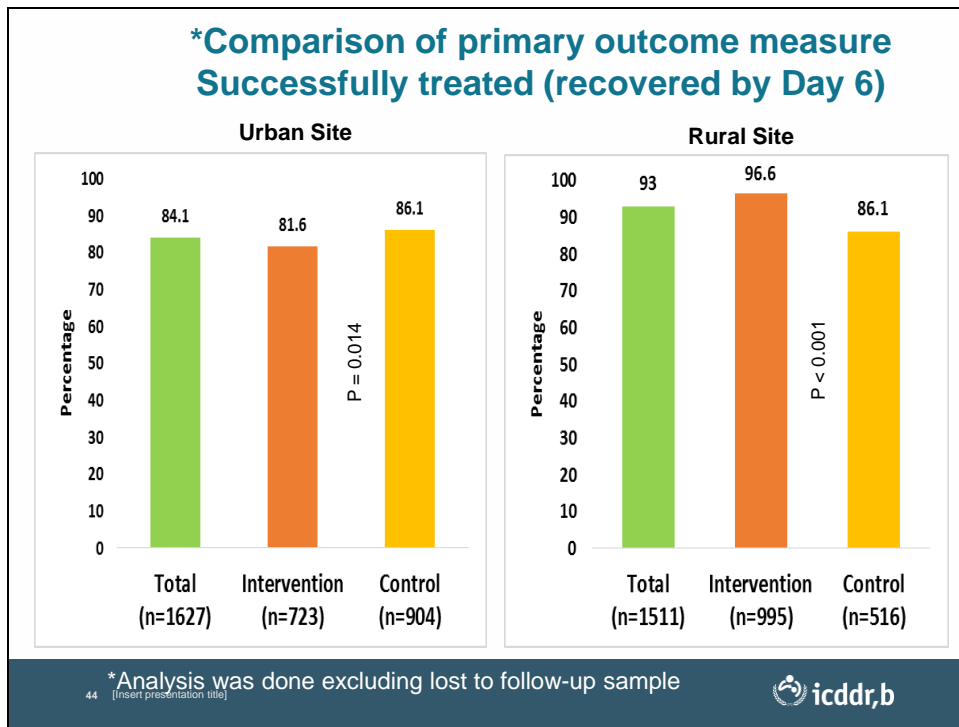
In preparation

4. Barriers to seeking timely treatment for severe childhood pneumonia in rural Bangladesh.

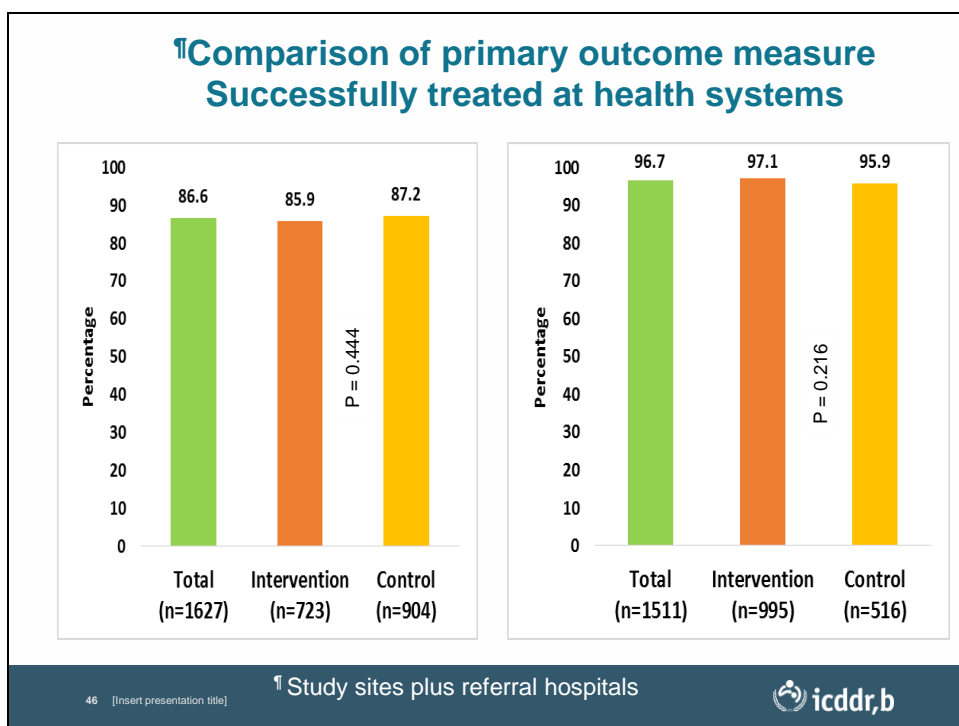
Authors: Kamal I. A. Chowdhury et al.
Submission: June 2020

Trial Results

Clinical Outcome



The data shows a high success rate of DCA (Intervention) and of usual care (control) in urban and rural study sites. While in the city region usual care (hospitalization) appears to reveal slightly better results, the opposite is the case in rural regions.



This table depicts the success rates of DCA compared to usual treatment within the

Bangladeshi health system including referral to the hospital system. Both management options are absolutely equivalent...provided the referral system is functioning, but Day-care is about **50% less expensive** (see table below)

A smaller investment in upgrading Day care facilities through development of trained human resources and procurement of supporting equipments could thus provide an effective alternative to hospital facilities


In summary: As predicted based on our previous studies the success rates turned out to be equal for DCA and control clusters, amounting to about 93% in the rural study area and 84.1% in urban trial sites. Outcomes-based on health system were identical

Economic outcome

Results

Cost-effectiveness analysis

Management strategy (Societal Perspective)	Cost per patient	Effectiveness per patient	ΔC ($C_{ET}-C_{DCA}$)	ΔE ($E_{ET}-E_{DCA}$)	Cost-effectiveness
Control cluster (ET)	USD 186.33	83.0%	-USD 91.37	+6.2%	Dominant
Intervention cluster (DCA)	USD 94.96	89.2%			

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Summary of economic Trial Findings

- ❑ **Key Findings:** Hospital management of severe pneumonia is a huge cost burden particularly for household due to indirect costs
- ❑ DCA is a cost-effective alternative compared to ET with 50% lower costs (Dominant)
- ❑ The new management approach (DCA) is economically viable and dominant alternative that has good value for money (DCA will save US\$ 91,040 per 1000 episode)
- ❑ Implementing this approach will cost ~\$9000 per facility per year, which can

reduce huge household costs burden and will improve care-seeking that will have an impact on reducing under-five child mortality.

Conclusions

The general progress, the quality and the results of the study were highly appreciated and well accepted by the professional audience and the health authorities of the seminar on December 1st 2019. It was felt that a primary focus of further work will be the extent to which the DCA is suitable for further scale-up in the Bangladesh health care system. There was an apparent consensus that DCA is indeed ready for scale-up; however, there was much discussion about the exact nature of the scale-up operation such as extent, process to follow etc. Such scale-up efforts would exceed the present project and involvement of the original sponsors UBSOF, UNICEF, BOTNAR and EAGLE. There was general agreement that the GOB will need to be the owner of a scale-up if it is to be successful and sustainable. Unicef showed interest to continue support of a next step contingent on the outcome of tangible programmatic impact.

The original effectiveness trial has now reached its successful end. The final activities lasting till end of 2020 will focus on publications and presentations at meetings. **The present report is therefore the last one to the EAGLE Foundation.**

On behalf of the research team I like to express my gratitude to EAGLE Foundation for its support of the international trial cooperators in this large and complex trial.

Future Developments:

The Govt. officials showed interest having daycare management of pneumonia and malnutrition scaled up throughout the Bangladesh health care system. This view also was shared by the president of the Bangladesh Pediatric Society.

We are working with UNICEF Switzerland, Dhaka UNICEF and the Govt. Officials to organise a Workshop by inviting local UN agencies, Govt. officials and relevant stakeholders in summer 2020 provided COVID -19 gets under control. It will be devoted to the scale-up.

Activities of N.Gyr during the first half-year of 2020(expansion)

N.Gyr was much involved in the data evaluation, the planning of the seminar and the budget control for the UNICEF, BOTNAR-EAGLE expansion phase grant. He was also monitoring the follow up of study results. The international communication was maintained with regular, at least 2 - weekly skype conferences, direct phone calls as well as e-mails and visits with sponsors in Switzerland. He also participated by skype at the 3 hours seminar on December 1st 2019. For health reasons, N.Gyr was unable to visit Bangladesh in 2019.

The finalisation of the trial with drafting and publishing the study results will take at least until end of 2020. An additional no cost extension is not foreseen. Potential Incurring additional unforeseen cost will be covered by my personal funds.

Annex: The title page of dissemination seminar, some news coverage in national print media



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Management of Childhood Severe Pneumonia with or
without Malnutrition using the Existing Health System of
Bangladesh**

Investigators

**Nur Haque Alam, Abu Syed Golam Faruque, M Jobayer Chisti, Shahnawaz Ahmed,
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Lutful Kabir, Md Shahidullah, Khaleda Islam, Tahmeed Ahmed, Minjoon kim, George J
Fuchs, Trevor Duke, Niklaus Gyr**

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Daycare approach

FROM PAGE 3

Dr Nur Haque Alam, senior scientist (nutrition and clinical services division) at icddr,b presented the result of the effectiveness trial of daycare approach.

"A smaller investment in upgrading day care facilities through development of trained human resources and procurement of supporting equipment [pulse oximeter for oxygen therapy and so on] could provide an effective alternative to hospital facilities," Dr Nur said in his presentation.

In her presentation on economic evaluation of the approach, Dr Marufa Sultana, assistant scientist at icddr,b, showed that average cost per patient is USD186.33 in hospital management of severe pneumonia while it is only USD 94.96, almost half, in daycare approach.

In another presentation, Dr Halida Hanum Akhter, professor at Johns Hopkins University in USA, highlighted that the daycare approach is feasible in the existing healthcare system with some changes.

In the question-answer session, speakers discussed the readiness of the healthcare facilities, especially of the union healthcare centres or community clinics, to adopt daycare services.

"Result of the study is convincing. Without government initiative, it would be tough to scale it up for the national level. There are challenges in readiness also," said Dr Daniel Frey, member of Unicef foundation board of Sweden, said in his speech.

Speaking as special guest, Prof Abul Kalam Azad, director general of the Directorate General of Health Services, said, "The problem with the union health centres is whether they are ready or not. Here, upazila health complexes, district and the tertiary-level hospitals could be good options to implement the daycare approach."

Presided over by Syed Monjurul Islam, acting executive director of icddr,b; Prof Marcel Tanner of Swiss Academy of Sciences; Prof Tahmeed Ahmed, senior director (nutrition and clinical services division) at icddr,b; and Dr Khaleda Islam, former director (primary health care) at DGHS, spoke at the event. among others.