

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; Start of patient enrolment in new study sites: 1.11.2017)

Project report IV to EAGLE Foundation, period 1.7.2019 till 31.12.2019

Date: 31.12.2019

Place of performance

07 study sites in Dhaka city and in 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 University of Kentucky, Lexington USA.

Investigators

Nur H Alam, Abu SG Faruque, Jubair Chisti, Shahjahan Ali, Tahmeed Ahmed, Shahnawaz 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 2019
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 by means of either Day care 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
Budget of 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 USD 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 hospitalization for antibiotic and supportive treatment such as pulse oximetry, oxygen therapy, nebulization, 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 who 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 aim of the present trial is 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 cluster randomized 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, Majikhpan involving the Health and Family welfare Clinics (HFWCs) under the Ministry of MoHFW
Control clinics (existing treatment protocol)	
Gandaria, Begumganj, Muradpur, Labagh, 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 or those who are self-referred will be treated at home with 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 fulfill the criteria of **severe** pneumonia.
- Children with **severe** pneumonia are referred directly to the hospitals/Day care clinics.

How Day care 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, nebulization 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 stabilized 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 development 2nd half 2019 and situation of the trial per Dec 2019

As previously reported UBSOF has kindly contributed CHF 142 thousand for the completion of the study including the diffusion activities by December 2019.

During the first and second half of 2019 (EAGLE report III + IV) we have completed the enrollment in March 2019 and thereafter the data cleaning and primary data analysis. Advanced data analysis is still in progress. We also have organized a steering Committee meeting in September 2019 at icddr Dhaka and as well successfully organized the planned dissemination seminar and workshop on 1st December 2019 after the world Pneumonia day 2019. The well attended session was widely appreciated and considered to have quite successfully met the goals. The final reports will be submitted by January 2020 and manuscript submission is planned by spring, latest midyear/end 2020.

Conclusions

The general progress and quality of the study were highly appreciated and well accepted by the professional audience and the health authorities of the seminar. A primary focus is the extent to which the DCA is suitable for further scale-up in the Bangladesh healthcare 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. Nevertheless 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 Govt. officials showed their 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 Dhaka UNICEF and the Govt. Officials to organize a Workshop by inviting local UN agencies, Govt. officials and relevant stakeholders in spring 2020.

Outcome

Clinical outcome: As predicted based on the previous studies the success rates turned out to be equal for DCA and control patients, amounting to about 97% in the rural study area and 86% in urban trial sites. Outcomes based on health system were identical. (see enclosed presentation)

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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- 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 impact on reducing under-five child mortality.

Activities of N.Gyr during the second half year of 2019(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 2020. For health reasons N.Gyr was unable to visit Bangladesh in 2019.

As the finalisation of the trial with drafting and publishing the study results will take another 6 months at least I am kindly requesting a no cost extension from EAGLE Foundation.

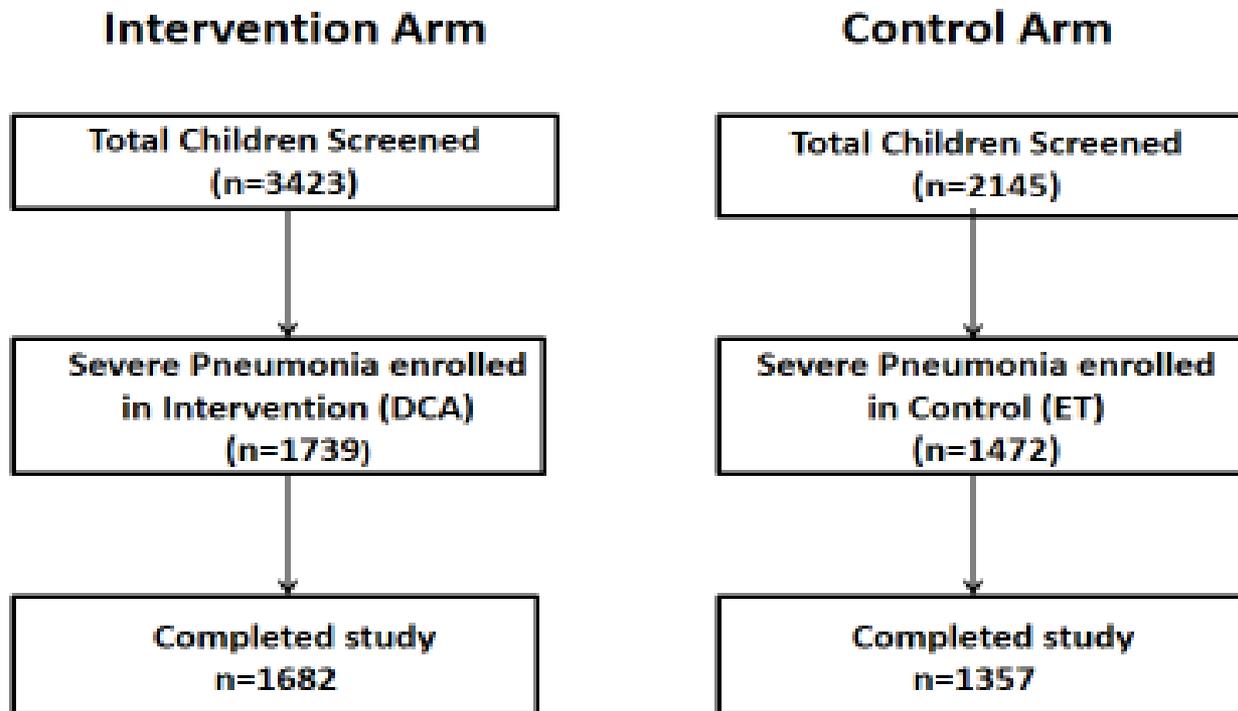


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Investigators

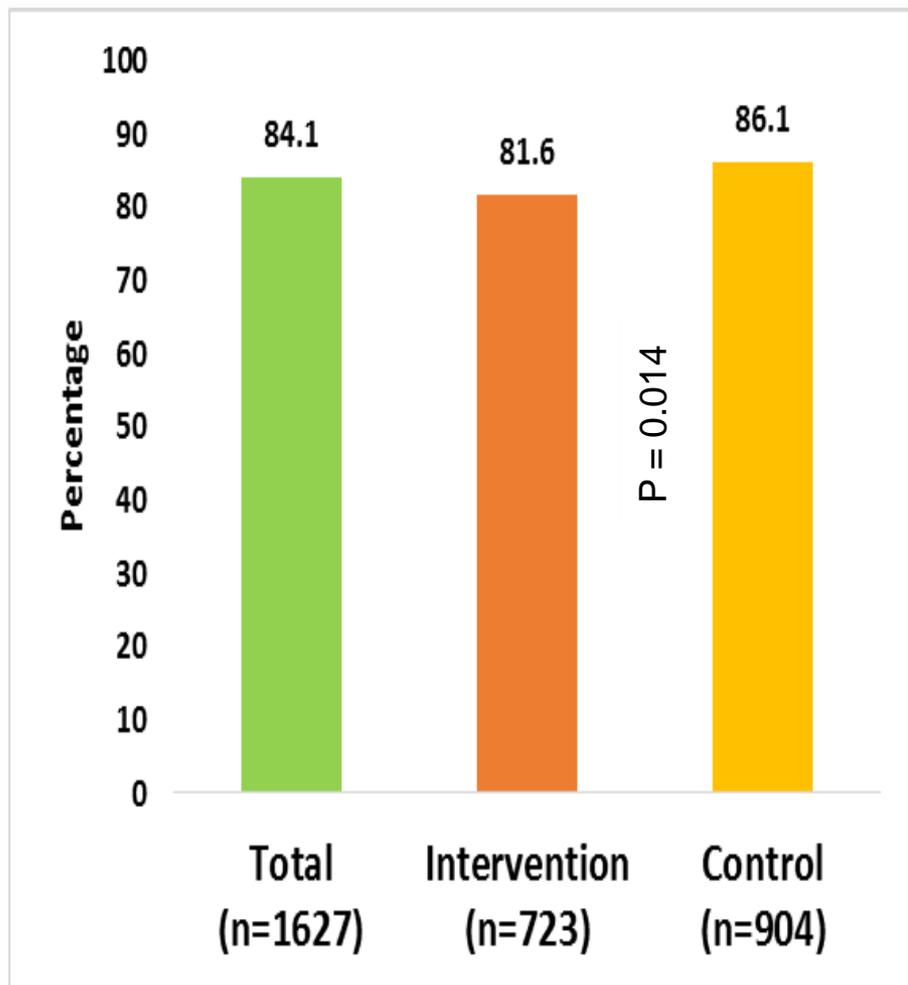
Nur Haque Alam, Abu Syed Golam Faruque, M Jobayer Chisti, Shahnawaz Ahmed,
Marufa Sultana, Sabiha Nasrin, Shahjahan Ali, Ruhul Amin, M Abid Hossain Mollah,
Lutful Kabir, Md Shahidullah, Khaleda Islam, Tahmeed Ahmed, Minjoon kim, George J
Fuchs, Trevor Duke, Niklaus Gyr

Trial Profile (combined urban and rural)

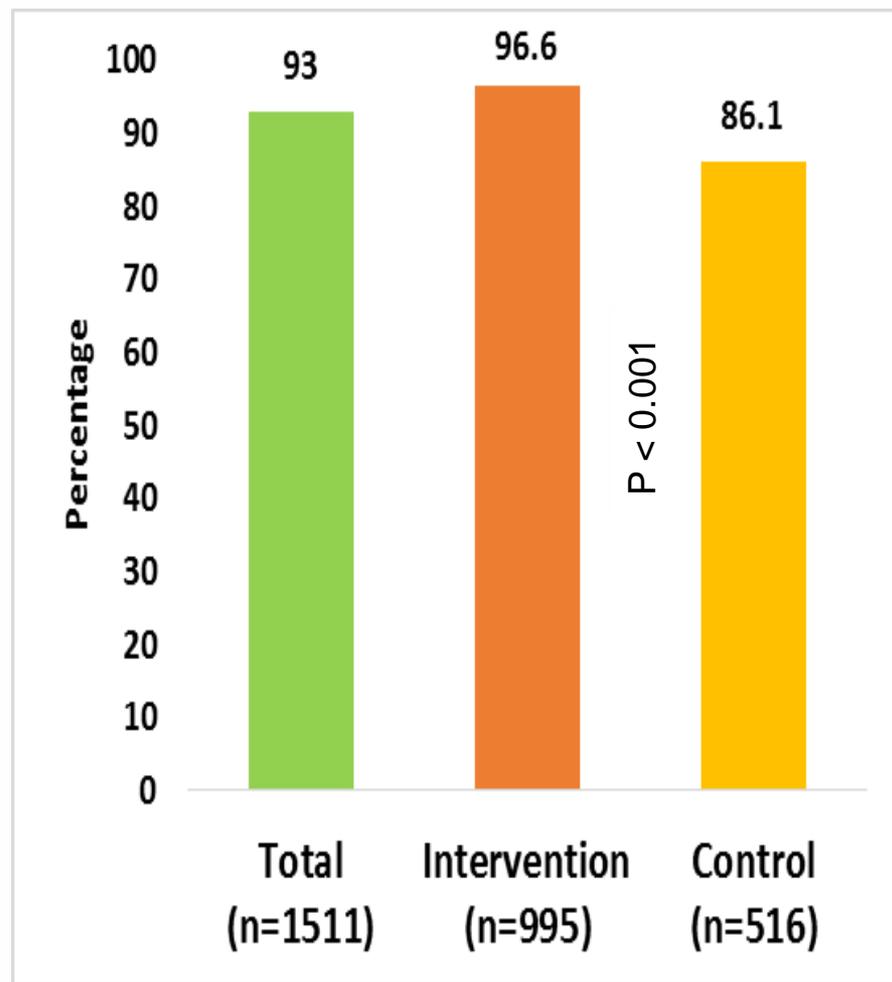


*Comparison of primary outcome measure Successfully treated (recovered by Day 6)

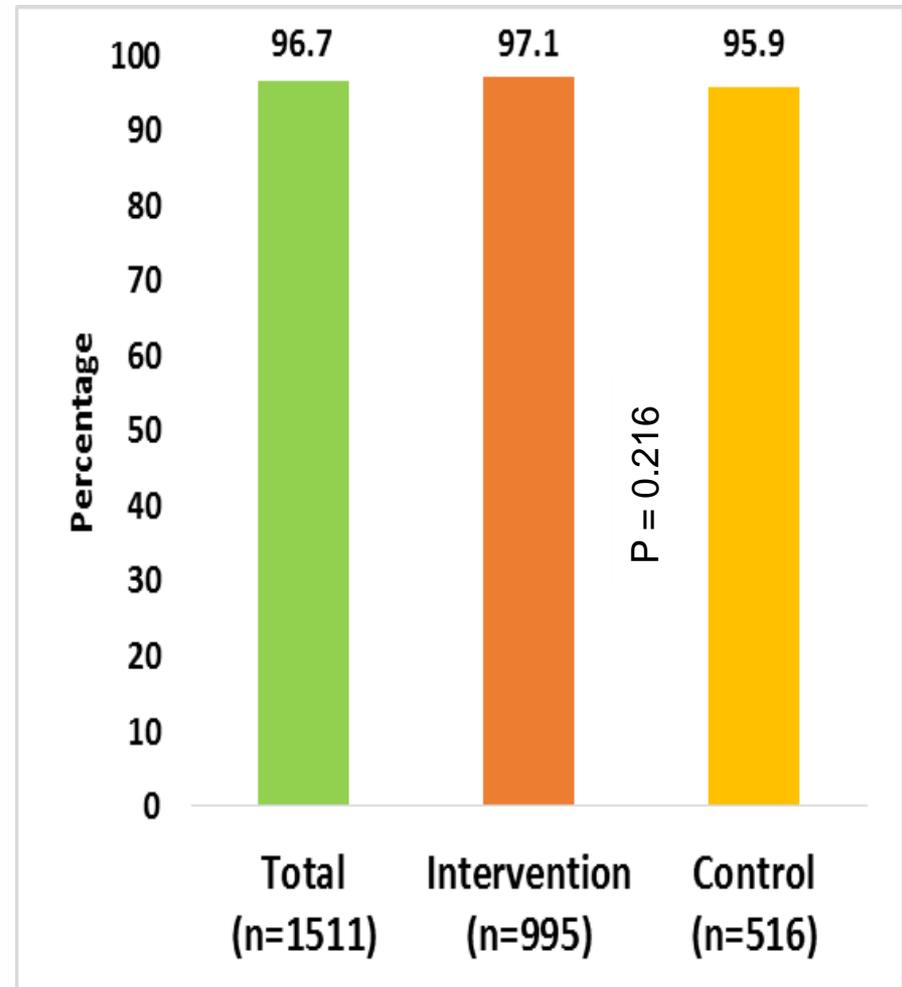
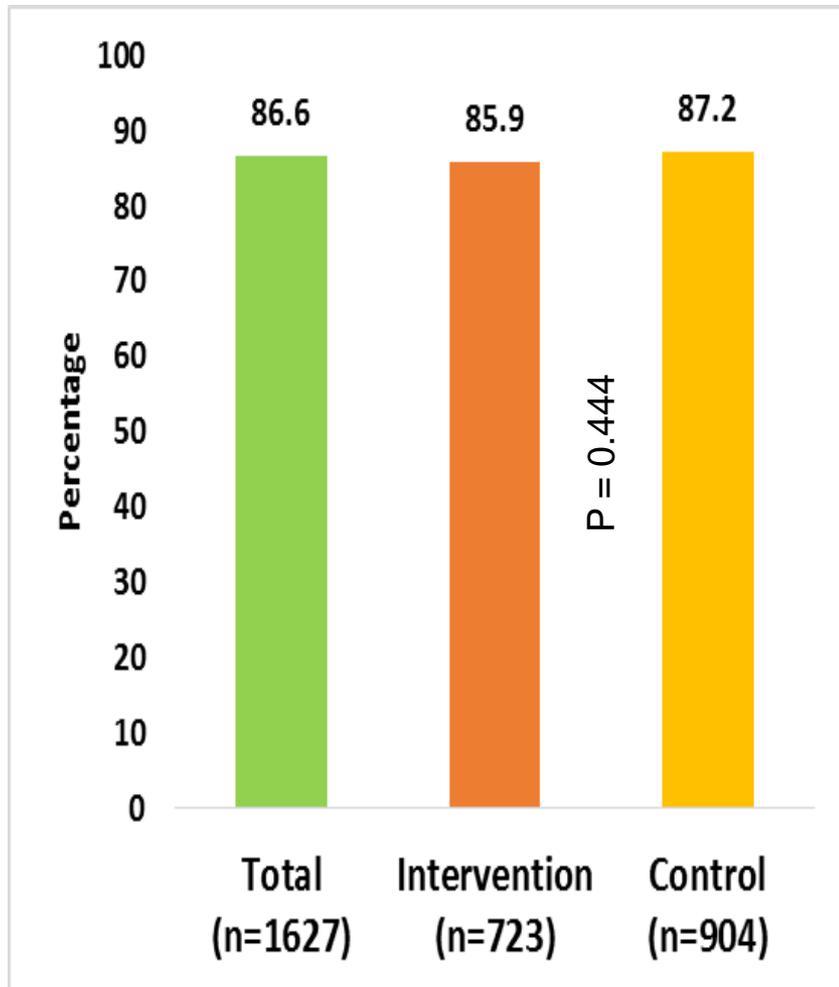
Urban Site



Rural Site



Comparison of primary outcome measure Successfully treated at health systems



Conclusion

The results from the current study and experience from our previous studies we conclude that 80 to 90% children with severe pneumonia with or without malnutrition can be treated in Day Care Clinics

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

Sponsors



THANK YOU

icddr,b thanks its core donors for their on-going support



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