# Minutes of the Board Of Trustees Meeting 2010 The INCLEN Trust International, New Delhi (India) (27<sup>th</sup> -28<sup>th</sup> February, 2010) At The INCLEN Trust International (IEO), New Delhi (India)

BOARD OF TRUSTEES:	SECRETARIAT STAFF & SPECIAL INVITEES:
ATTENDEES:	SECRETARIAL STAFF & SPECIAL INVITEES:
1. Demissie Habte ( <b>DH</b> ) Chair, Presiding Officer	Narendra K. Arora (NKA)     Executive Director – INCLEN Trust     International & CHNRI
2. Amr Hassan ( <b>AH</b> ) President, INCLEN-Africa	2. R. M Pandey ( <b>RMP</b> ) Special Invitee
3. Rajit Roy Choudhury (RRC) BOT Member	3. Sunil Sazawal (SZ) Special Invitee
<ol> <li>Manuel Emerson Donaldo (MED)         Coordinator Elect,         Representing Osman Sianipar (OS), INCLEN-Asia     </li> </ol>	4. Vishwajeet Kumar (VK) Special Invitee
5. Sergio Munoz (SM) President, LatinCLEN	5. Stephanie Combs (SC) Chief Finance Officer, INCLEN Inc.
6. Laura Sadowski (LS) Representing Peter Tugwell (PT), CanUSACLEN	6. Poonam Jain ( <b>PJ</b> ) Director Finance, INCLEN Trust International
7. A. K. Niswade ( <b>AKN</b> ) President, IndiaCLEN	7. Manoj Kumar Das (MKD) Director Projects, INCLEN Trust International
8. Jonathan Lee Simon ( <b>JS</b> ) BOT Member	8. Simi Khan ( <b>SK</b> ) Grant Administrator, INCLEN Trust International
Francois Chapuis ( <b>FC</b> ) 9. President, RECIF-Euro MedCLEN	9. Debjani Samantaray ( <b>DS</b> ), Operations Manager, INCLEN Trust International
Jin Xuejan ( <b>JX</b> ) 10. Representing Jiyao Wang (JW), ChinaCLEN	
<u>Unable to attend</u> Marcel Tanner ( <b>MT</b> ) BOT Member	
Palitha Abeykoon ( <b>PA</b> ) BOT Member	

# $\label{thm:continuous} \textbf{Summary of Significant and action items resulting from the meeting:}$

Agenda Items	Decisions / Items	Action to be taken		
Registration of CLENs as Legal	INCLEN-Africa,	<ul> <li>Instead of seeking full, legal status in</li> </ul>		
entities	LatinCLEN	every member country, the CLENs		
		may devise alternative ways to		
		formalize their legal status		
		• "UN Registered Observer Status for		
		NGOs" to be explored for this.		
Induction of NGOs as CEUs	All CLENs	Define "Affiliate members" status to be conferred on prospective NGOs under		
		this proposal.		
		• Clarify Affiliate member status, rights, responsibilities, eligibility criteria.		
		Invite recommendations from existing members of CLENs / CEUs and other		
		network members.		
MOUs and Partnerships	INDEPTH	<ul> <li>Meeting scheduled between INCLEN Trust, INCLEN-Africa and INDEPTH, in May 2010 to discuss final steps of partnership.</li> </ul>		
		• INCLEN-Asia, INCLEN-Africa and		
		IndiaCLEN to evaluate and increase		
		intensity of involvement in the		
		INDEPTH network.		
	JCE	Collate information from all CLENs and publish a bi-annual newsletter via JCE.		
	PHFI	Provide update on prospective MOU between PHFI and INCLEN.		
	Duke University	• Another proposal to be submitted clearly outlining the limitations of the "R-O-R" study.		
	IGIB	Provideupdateonstatusof     prospective MOU between IGIB and     INCLEN.		
	Jamia Milia Islamia	Provideupdateonstatusof     prospective partnership between Jamia     Milia Islamia and INCLEN		
Guidelines to develop new	IEO-Delhi, CanUSACLEN,	Draft an institutional policy on		
partnerships	INCLEN-Africa	research data ownership, sharing, access and application.		
		Refer Partnership Assessment tool		
		developed by the Centre for Global		
		Health Research, Canada for this.		
IPHIDE Final report	IEO-Delhi, IndiaCLEN	Publish the final report		

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Network expansion and consolidation	Wits University	<ul> <li>INCLEN-Africa to review and provide update on application status of Aberdeen and Botswana University</li> </ul>
	Japan CEU	INCLEN-Asia to review and provide update on application status
	B.P.Koirala Institute of	INCLEN-Asia to review and provide
	Health Sciences	update on application status
	IndiaCLEN	<ul> <li>IndiaCLEN to declare status of prospective MOUs between IndiaCLEN and MCH-Star-supported four new CEUs.</li> </ul>
INCLEN Capacity Building Initiative	All CLENs	<ul> <li>LatinCLEN to contribute in this initiative from its prior successful experience</li> </ul>
		• CLEN Presidents to facilitate the TAG in providing intellectual input to develop and mentor the "Learning-By-Doing" initiative of IndiaCLEN.
		<ul> <li>Prepare a list of courses conducted by CEUs/CERTCs across network.</li> </ul>
INCLEN Website and the Network directory	IEO-Delhi, All CLENs	<ul> <li>INCLEN website to be revamped</li> <li>Upload sample size calculation software.</li> </ul>
Criteria for CERTC accreditation with IEO	IEO-Delhi	<ul> <li>SM to draft criteria for accreditation of CERTC.</li> </ul>
Standard Operating Procedures	IEO-Delhi	Draft SOPs to be circulated to Board members and approval sought before implementation.
Setting up of INCLEN Trust Development Fund	IEO-Delhi, BOT	• The INCLEN Trust Development Fund to be set up to optimally utilize funds and balance overheads of completed projects/programs.
Financial Matters	IEO-Delhi	• A formal Investment Policy is to be developed and presented to the BOT for ratification.
Strategic matters - Reinventing INCLEN	All CLENs	A document to be prepared by IEO- Delhi on "Strategy to Reinvent INCLEN" to assist in communicating the consistent message throughout the network. Document to be prepared and ratified by the Board of Governors.

#### WELCOME BY INCLEN CHAIR AND INTRODUCTION TO IEO STAFF:

Board meeting commenced at 10:00 a:m IST at IEO. Board Chair, **DH** called the meeting to order and welcomed all present to the new INCLEN Executive Office. Board Members, special invitees and IEO staff present, were introduced to each other. **JX** apologized for absence of Jiyao Wang (President, ChinaCLEN) due to unavoidable circumstances. **FC** apologized for being unable to attend the BOT 2009 Meeting. Agenda for BOT Meeting 2010 was presented, reviewed, motioned and approved by consensus.

#### **MINUTES OF MEETINGS:**

- i) BOT Meeting (27 & 28 Feb 2009): Minutes of meeting were reviewed by Board and approved unanimously.
- **ii)** Finance and Executive Committee Teleconference (22 July 2009): This teleconference was regarding shifting of IEO-Delhi office to its new premises and issues related to status of IEO-Philadelphia. Minutes of meeting were reviewed by Board and approved unanimously.
- iii) BOT Teleconference (19 August 2009): This meeting related to the audit for the financial year 2008 of INCLEN Inc. and The INCLEN Trust International Inc. and also related to status of the Philadelphia office. A follow up was done with JS and LS (On behalf of PT) to provide update on—"Moving back within University structure". The discussion was regarding whether a US university affiliated to INCLEN would be willing to host the minimal Executive office structure to legally maintain the structure there to avail the benefits thereof. JS affirmed that Centre for Global Health and Development, with permission of the Dean, can provide space required for housing minimal administrative staff court. LS commented, that PT has also enquired for options with the University of Ottawa. Minutes of meeting were reviewed by Board and approved unanimously.
- **iv)** Finance and Executive Committee Teleconference (29 Sept 2009): This meeting was regarding Audit reports of The INCLEN Trust International (New Delhi) for FY 08-09. Minutes of meeting were reviewed by Board and approved unanimously.
- v) Minutes of Finance and Executive Committee Teleconference (5 Nov 2009): This meeting was regarding Form 990 of INCLEN Inc. and INCLEN Trust International Inc. and to be submitted to the US Revenue Department after Board approval. SC commented that the returns had been duly explained to the Board. The Finance and Executive committees were made aware of the changes at IEO-Philadelphia and matters were finalized. Minutes of meeting were reviewed by Board and approved unanimously.

#### BOT 2009 - ACTION TAKEN REPORT (ATR) : NKA spoke of the progress made :

#### a) Registration of CLENs as Legal entities:

Three CLENs (INCLEN-Africa, INCLEN-Asia, LatinCLEN) out of 7 remain to be registered.

Benefits, Considerations and Challenges faced in registering CLENs as Legal entities were highlighted. This was based on feedback received from CLENs already registered e.g. IndiaCLEN. CLEN representatives discussed challenges faced within their own areas, government requirements, problems with multi-country members, international funder/donor issues, current political and economic factors, and other globally and regionally pertinent issues.

**Benefits cited were:** Better democratic functioning with setting of new mandates and activities, increased accountability as per monitoring mechanisms of the laws of the land, increased donor confidence especially in light of activities such as terrorism, better standards of financial control, distinct financial advantages and, expansion of network and member base.

**Certain considerations were:** It would be highly desirable to establish link between the parent body of INCLEN and CLENs undertaking registration. To achieve this, it was advised that Articles of other CLENs and Article of The INCLEN Trust International (India) can be shared. Care should be taken to ensure conformity with laws of the particular land. It would be appreciated if basic mandate of all CLENs is kept similar to the mission and vision of INCLEN. There is a need to focus on high quality financial controls and monitoring mechanisms within all CLENs to maintain credibility with members and other stakeholders.

CLEN registration was thought to be important especially in light of the imminent evolution of INCLEN. This would smoothen financial difficulties in securing and disbursing project funds by the CLENs. Some alternatives suggested were, establishing a formal status within the University structure to enable easier receipt and disbursal of funds for CEU activities. However, some autonomy would be needed to maintain continuity without risking University interference or discontinuation. Else the Charter of a new member institution could reflect wider geographic activities of the entity, hence indicating relation with the parent body. The Chair suggested referring to the existing "UN Registered Observer Status for NGOs", to explore the option of regional CLENs taking on an Observer Status and avoiding financial hassles arising due to lack of member registration. This option was thought especially relevant for INCLEN-Africa and LatinCLEN. To assist in CLEN registrations, INCLEN would provide USD 2,500 for each CLEN.

#### Challenges cited and possible solutions were :

Key challenge of CLEN registration is particularly faced by those CLENs that are multi-country. In the absence of any global law stating that registration in one country validates legal existence of an organization in other countries, a framework needs to be established. All CLENs, instead of seeking full legal status in every member country, may devise alternative ways to formalize their CLEN status.

The legal expert in IEO recommended that CLEN articles should clearly mention about their member CEUs/CERTCs and countries and have the provision of additions as the network expands. Else, CEUs/CERTCs of a particular country may give an undertaking to follow and adapt the CLEN Charter by signing a formal agreement / MOU with the CLEN Secretariat. This will impart a certain degree of legality to entities and confidence to funders. Yet another option may be individual country registrations with same Charter as that of CLEN.

Some pertinent comments made were: AKN cited the example of IndiaCLEN functioning successfully as a separate registered legal entity. AH highlighted INCLEN-Africa facing difficulty in registering as an International NGO. It was suggested that keeping the same Charter of INCLEN-Africa, they may register in a less stringent country environment like South Africa, Zambia or Zimbabwe etc. SM commented that for LatinCLEN, registration in one country and having multi-country operations was feasible but expensive. LS commented on smooth-functioning of CanUSACLEN despite rotating leadership and being registered in USA but operating from Canada. The board discussed the matter on Day 1 and 2 of the BOT Meeting.

(b) Induction of NGOs as CEUs: SK elaborated on this issue through a presentation. The discussion pertained to the potential of including NGOs as network members, to enlarge the geographic areas for research and capacity building and utilize opportunities with other suitable partners, rather than just through the existing network of Medical and teaching institutions. Some advantages cited in doing so were, network expansion, building a cadre of secondary and tertiary health researchers, leveraging the knowledge and skills of outstanding NGOs, catering to marginalized populations etc. The successful example of IPEN was highlighted to show the relevance and importance NGOs could assume in the existing Network. Certain criteria were suggested for NGOs to be recognized and accredited as INCLEN CEUs. This concerned their legal status, mandate, expertise of existing human resource, infrastructure and financial viability.

The Board cautioned against certain NGOs that may try to exploit their membership in the Network to gain business mileage. A separate group of entities was suggested to be created within INCLEN framework instead of recognizing NGOs as full-fledged CEUs. The Board suggested creating "Affiliate members" called CEIs (Clinical Epidemiological Institutions) / FEUs (Field Epidemiological Units) / AIMs (Associate INCLEN Members), having the criteria for health research but not necessarily clinical epidemiology and capacity building.

The Articles of Incorporation of INCLEN Trust International were referred to in the Board's presence and it was found that an institution need not be in a University structure to become a member, however it needed to provide training. 'Honorary membership" in the article was thought to be close to the definition of Affiliate Membership, and hence required further exploration. NGOs like "Save the Children", and institutions like PHFI (Public Health Foundation of India) having sophisticated resources and undertaking good quality research, could thus become prime training institutions. In conclusion, the Board suggested that such "Affiliate members" status be first defined, their rights/responsibilities and eligibility criteria clearly stated, and recommendations invited from the existing Network members, especially from the CLENs and CEUs.

#### (c) MOUs and Partnerships:

i)Health Technology Assessment International - It appeared that Health Technology Assessment International were interested only in keeping INCLEN informed of their activities.

ii)INDEPTH - Significant progress has been made in the last one year to develop this partnership. A meeting has been scheduled between INCLEN, INCLEN-Africa and INDEPTH, in May 2010 to discuss final steps of establishing partnership.

iii)JCE - Initiative has been taken up by **PT** and **Tony Dans** from Philippines. A special issue on the IndiaCLEN research is expected in 2010. Subsequent to a series of teleconferences, a tentative list of 5 articles has been prepared. **NKA** discussed plans of collating information from various CLENs and publishing a bi-annual newsletter via the JCE. They have allowed six to eight leaves to the INCLEN Newsletter in their issue.

A Publication Officer and Advocacy and Communication Officer are to be in place in the IEO for facilitating this process.

## d) Network Expansion And Consolidation:

New CEU/CERTC applications submitted were discussed:

i)Wits University- Applied to INCLEN-Africa for upgradation to CERTC status. This was to be discussed further by **AH**.

ii)Japan CEU- Applied to INCLEN-Asia for induction into the CLEN.

iii)B.P.Koirala Institute of Health Sciences - Applied for CEU status to INCLEN-Asia

iv)IndiaCLEN - With support and concurrence of USAID, MCH-Star and IndiaCLEN, 4 new CEUs are being established at 2 strategic locations - Uttar Pradesh (UP) and Jharkhand. 3 MOUs have been signed and 1 is pending between IndiaCLEN and MCH-Star. Faculty at these CEUs shall undergo training to bring them up to requisite CEU standards.

#### (e) INCLEN Capacity Building Initiative (With inputs from LatinCLEN):

LatinCLEN has the longest, most versatile experience in distance-education training. Hence **SM** presented on the initiatives taken by LatinCLEN in this direction, through the CLEN progress report on Day 2 of the meeting. IndiaCLEN "Learning By Doing" initiative in Capacity Building was highlighted. In this a Gap analysis has been conducted and competencies drafted. CLEN Presidents were requested to facilitate the formation of TAG to provide intellectual input in developing and mentoring this program.

#### **OVERVIEW OF ACTIVITES:**

#### **COMPLETED PROJECTS:**

#### 1. IndiaCLEN Program for Health Intervention and Development (IPHIDE):

This project was carried out by IndiaCLEN with USAID funding and completed on 30<sup>th</sup> September 2009. It was a multi-site and multi-investigator driven project in India.

Its final report has been prepared, submitted to Boston University and USAID. This report will be printed and disseminated to key stakeholders.

**2.** Determinants of Undernutrition and Assessment of Management at Different levels of Healthcare: This Project was carried out by INCLEN and IndiaCLEN with funding from WHO and USAID (MCH Star). The project is in final stage of report preparation.

#### **ONGOING PROJECTS:**

- 1. Neuro-developmental disabilities among Children in India: This project is being carried out in partnership with University of Pennsylvania, Stanford University, University of Wisconsin. It aims at establishing criteria and tools to identify children with developmental disabilities. The project is being funded by Autism Speaks, National Trust (GOI), and NIH, INCLEN Inc. Currently efforts are being made for resource pooling and taking up similar activities funded by Autism Speaks. Currently the Consensus Clinical Criteria, the modules and the Operational manual have been finalized. Field trials for the tools developed will start in the next few months.
- **2. SAPNA III** (South Asian Pneumococcal Alliance and the Invasive Bacterial Infection Surveillance Group): This project is being carried out by IndiaCLEN in partnership with Johns Hopkins University and is operational in India, Nepal, Sri Lanka. It is funded by Pneumo-ADI and the Hib Initiative. It is expected to end by March 2010
- **3. Achieving MDG5:** INCLEN Program Evaluation Network Pilot Study into Governance of Public Health System in Ethiopia (Particularly in relation to Maternal Health). This project is being carried out in partnership with Addis Ababa University and is funded by IDRC (Canada). Under this project currently, data has been collected, interim analysis completed and draft report is under preparation. An analysis workshop under this project was also organized in January 2010.
- **4.** The National Certification Committee for Polio Eradication (NCCPE): The Secretariat of NCCPE is supported by the Ministry of Health and Family Welfare (Government of India). On 20<sup>th</sup> March 2009, the 14<sup>th</sup> Annual Meeting of the NCCPE was organized at IEO, New Delhi. The current status of polio in India are reviewed by the Secretariat and pertinent recommendations made to the Government of India and National Polio Surveillance Program.
- **5. Measurement & Determinants of Childhood Obesity:** This project is funded by INCLEN Inc.(Philadelphia) and efforts are underway for further fund generation. Three proposals have been developed so far. One for ICMR and CIHFR Joint RFA; the full proposal for this is due for submission. Another proposal has been developed for ICMR. A proposal for DBT is under development for dealing with the genetics and epigenetic issues related to childhood obesity. All the activities are limited to India.
- **6. Influenza Awareness, Preparedness and Response -** A program to train Physicians across the India: This program proposes to train physicians across India to control mortality and morbidity due to influenza. The project will continue till August 2010. The project is being undertaken in partnership with Ministry of Health (Govt. of India), ICMR, NIHFW, AIIMS and NICD. Funding is available from ICMR and CDC. Progress of this project was discussed in the Annual CDC Influenza meeting at Bangkok on 27<sup>th</sup> August, 2009.

#### **NEW PROJECTS LAUNCHED:**

- 1. Study to Evaluate the impact of Topical Application of improved oil and/or improved skin care practices on Neonatal Mortality: This is a controlled, four armed cluster randomized trial being carried out in rural districts of Rae Bareli (Uttar Pradesh, India). This is being carried out in partnership with ITRC Laboratory (Lucknow), Department of Dermatology, University of California, USA. Bill & Melinda Gates Foundation (BMGF) is funding this project. HMSC clearance for this project from ICMR is awaited.
- **2.** Efficacy of Zinc in treatment of severe and very severe pneumonia in hospitalized Children (2-24 months of age): This project is being carried out in partnership with AIIMS, New Delhi, and is funded by John Hopkins University and WHO. The duration of this project is from October 2002 to April 2010.
- **3.** Influenza Disease Burden in Rural Communities in India (Community-based site of Ballabhgarh, Near Delhi): The project is carried out with CDC (Atlanta) funding and in partnership with AIIIMS. The project is in preliminary stage of starting field study.
- **4. Direct & Indirect Protection by Influenza Vaccine given to Children in India:** This project is also carried out with CDC (Atlanta) funding and in partnership with AIIMS. Trials are being carried out in the community setting of Ballabhgarh. The agreement with CDC has been signed and the project is in preparatory phase.
- **5. Environmental/ Genetic Triggers of Premature Birth :** This project will be carried out in Rae Bareli district of Uttar Pradesh(India) with BMGF funding, in partnership with The University of Iowa, USA. IRB clearance is awaited for this project.
- **6. Hib Sentinel Surveillance in Uttar Pradesh (India) :** This project is carried out with USAID funding, in partnership with CSMMU, Lucknow and John Hopkins University.
- **7. Hib Sentinel Surveillance in New Delhi (India):** This project pertains to reducing Meningitis related deaths. This project is being carried out with USAID funding in partnership with AIIMS and KSCH (Kalawati Saran Children"s Hospital), New Delhi
- **8.** International Fetal and Newborn Growth Standards for 21<sup>st</sup> Century (Multi-country study): This project will be carried out with WHO funding (Through University of Oxford), in partnership with Ketkar Hospital (Nagpur, India). The project is in the preparatory phase.
- **9. SEA Regional Conference on Epidemiology:** This international conference is funded by CDC (Through PHMI in India) and is to be held in Delhi on 8-10 March, 2010. INCLEN is responsible for organizing this meeting in partnership with WHO and seven other organizations.

# **NEW INITIATIVES PLANNED:**

- 1. Respiratory Infection Control as strategy to reduce the burden of respiratory and other health care associated infections in children in India: This project is submitted to CDC (Atlanta) for funding, in partnership with AIIMS (All India Institute of Medical Sciences, New Delhi) and Maulana Azad Medical College (New Delhi).
- **2. Respiratory Infection Control training in Indian Medical Institutions (India) :** This project is submitted to CDC (Atlanta) for funding .
- **3. Brain To Society Surveillance System to Prevent Childhood Obesity :** This proposal has been developed in partnership with McGill University (Canada), ICMR (Indian Council of Medical Research) and CIHR (The Canadian Institutes of Health Research) .The Letter Of Intent for this project has been selected and the full proposal is due on 1<sup>st</sup> May 2010.
- **4. Brain-to-Society-System Science Project** A Multitier Knowledge Basis for Local, National and Global Action for a Lifestyle that Human Biology Can Handle/Healthy Eating Component: This proposal developed in partnership with McGill University, is submitted for NIH funding. Project application was submitted in January 2010 and the outcome will be known in the next 2 months.
- **5. Obesity in Children in India** (5 Site study in India): This project is submitted to ICMR for funding. The outcome will be known in May 2010.

- **6. Study of genome wide DNA Methylation in Obesity among Children :** This proposal is under development with multiple partners and will be submitted to DBT (Department of Biotechnology, India) for funding.
- **7. Building sustainable research capacity for safer and better health care in Africa:** This project is developed by a consortium lead by WHO (World Alliance For Patient Safety) and is submitted to European Union (FP 7) for funding. INCLEN-Africa is a consortium member and the study is proposed for seven countries. The project proposal has been submitted for review.
- **8.** Assessment of burden of unsafe patient care in India A patient safety research capacity building initiative through learning-by-doing approach: This project will be carried out in partnership with PGIMER (Post Graduate Institute of Medical Education and Research) and AIIMS. Project proposal is submitted for review to WHO and Government of India.
- **9. Assessment of Injection Safety in Indonesia :** This project will be carried out with WHO-SEARO funding, in partnership with INCLEN-Asia and Ministry of Health, (Indonesia). The proposal is under consideration.
- **10. Hypertension and Pranayam -** A field trial for the evaluation of efficacy of Yoga and Pranayam in Hypertension: This project will be carried out with Patanjali Yogpeeth, Haridwar (India) funding. This project is in its conceptual phase.
- **11. IMNCI** (Integrated Management of Newborn and Childhood Illnesses in India) Concurrent Implementation & Program Evaluation (Baseline survey in 2008 has been completed): This project will be carried out with funding from UNICEF, DFID and NIPI funding, in partnership with Ministry Of Health and Family Welfare (MOHFW-GOI). This project is currently in its discussions phase.
- **12. Global Model Injection Centers** "Model Injection Centers A Global Program to improve injection practices in LMICs: This project will be carried out in partnership with all INCLEN Regions. On 30<sup>th</sup> September 2009, one phase of the project was completed under IPHIDE Project. Current phase of the project is in its conceptual phase. Potential funding options are BMGF, GAV.
- **13. "Vitamin B12, Iron and Folic Acid Deficiencies and related Anaemia -** A study in two states of India: This proposal has been submitted to GAIN and MCH-Star for funding. IPEN partners and Boston University shall be collaborators for this proposal.

**NKA** identified the following main thrust areas where INCLEN can assume local, regional and global leadership, which it is trying to develop in a program mode :

- 1. Childhood Obesity: The aim is to pre-empt and address this issue before the problem magnifies for resource-constrained LMICs as it has been for the developed world. An attempt is being made to build a story around this concept and thence take global leadership. To translate this philosophy into meaningful, cutting-edge research, INCLEN has started ground work to set a surveillance site for a 200,000 population in the district of Palwal near Delhi. Another 160,000 will be added in Phase II. The focus remains on children to begin with but with the involvement of parents, the adult chronic disease agenda will also be pursued.
- **2. Neuro Developmental Disabilities (NDD) :** A screening tool for NDD is developed, and validated. Similarly consensus clinical criteria for autism, ADHD, epliepsy and cerebral palsy have been validated. The tools developed will be made available in public domain and uploaded on the website for easy and free access. INCLEN will now be approaching the community level to estimate the disease burden. In Phase I, India is the study site. In Phase II, six to eight countries in the INCLEN network will be involved for this study.
- **3. Patient safety and Quality of Care:** The aim here is to try and develop instruments to assess and design suitable interventions on the issue of Patient Safety in resource constrained environments.
- **4. Governance of public health systems :** The Ethiopian project experience in this context is proving to be a very educational. The Ethiopian experience has helped to develop instruments that can be used at other sites and can help in assessing and influencing governance in public health systems at national and regional levels.

**5.** Additional Studies: NKA highlighted the importance and economy in leveraging the already-set cohorts of newborns at Shivgarh (Lucknow, India) and Pemba (Tanzania) sites for additional studies. **6.** Other areas being explored for research possibilities: Outbreaks of infections like Avian Flu, SARS Virus, H1N1 etc. Currently work in these areas is being pursued in conjunction with CDC through 4-5 sites. To facilitate smooth and simultaneous research endeavors in different parts of the INCLEN network, efforts are on to set up a cooperative agreement between CDC (Atlanta) and INCLEN Inc. Since NKA"s nomination for the SAGE (Strategic Advisory Group of Experts) in WHO, there has been additional interest in research on immunization activities.

The BOT congratulated the immense research endeavors undertaken by INCLEN Executive Office. However it felt that INCLEN is lagging in network research activities beyond India; with most network activities taking place in India. In response to these doubts, NKA explained that for the first one to two years when IEO shifted to Delhi, its survival was questionable and the IEO was in a fragile state then. Thus it was best to strengthen presence in home ground, and then undertake gradual expansion. As now IEO is in somewhat better shape at its home ground, expansion of INCLEN activities will be encompassing other parts of the network as well. Currently, 3 projects outside of India are underway:

- 1.Injection Safety Study in Indonesia
- 2. Capacity Building Program in INCLEN-Africa
- 3. Governance Study in Ethiopia.

In trying to expand the activities in the network, following problems are encountered: There is confusion for funding agencies about whom they should deal with, The Institution or The Organization. Secondly, in absence of registered and legal status for the CLENs, it is difficult to route funds received through them; but if Institutions or Universities are dealt with instead, INCLEN loses out on its rightful credit sharing. The core support and overheads issues of INCLEN too are manageable. INCEN currently has modest and negotiable overheads. An important issue of relevance at present is on building confidence of funding agencies in INCLEN as a viable option that delivers high quality and timely service. SS commented that currently from the Government of India perspective, INCLEN is regarded as the organization of choice for undertaking large scale program evaluation. Thus such niche` needs to be created in all CLENs. ChinaCLEN has particularly been able to establish itself as a strong and respectable network within the country.

**RRC** encouraged the Board to identify themes other than Pediatrics, wherein INCLEN could be identified as a leader. Two challenges were identified in these endeavors: Need to reproduce the success and level of activity in India, across CLENs; and ensuring that the results of completed projects are being utilized for welfare purpose. **LS** expressed her concern for some core support to find its way to INCLEN to impart the organization continuity and sustainability. This shall encourage IEO to make additional efforts of initiating activity in other CLENs as well.

#### PROGRAM DEVELOPMENT: PARTICIPATION IN MEETINGS/OUTCOMES:

More than twenty meetings were attended in the past year by NKA and other staff. Corpus funds were not used for this purpose. Purpose of these meetings was to continue exploring possibilities of new programs where INCLEN network can be involved, to broaden the visibility of INCLEN and to establish its strong presence and dynamism in research.

#### EXPANDING NETWORK: MOUS/PARTNERSHIPS WITH OTHER ORGANIZATIONS:

i) PARTNERSHIP WITH Child health and Nutrition Research Initiative (CHNRI): CHNRI is one of the 7 initiatives of Global Forum for Health Research (GFHR), focused on Child Health and Nutrition

related research. In 2001 it started with initial funding from World Bank. In 2006, it was registered in Switzerland. Following approval from the BOT a MOU has been signed between Child Health and Nutrition Research Initiative and INCLEN. The CHNRI Secretariat has moved from ICDDR,B (Bangladesh) to IEO as of January 2010, where it will be hosted for the next 2 years. Robert Black is the Chair, **NKA** is the Executive Director and **MKD** is the coordinator of CHNRI. A Communication and Publication Officer is soon to be hired as well. **DH** has been co-opted as the Board Member of CHNRI. Similarity was drawn between the visions and missions of CHNRI and INCLEN. Their compatibility and ability to impart mutual strength was emphasized as Child health is a priority for both organizations and the synergy created between the two organizations can make an impressive momentum for generating a global presence. CHNRI has been struggling to maintain core funding and hence the attention has shifted to IEO to manage core activities and keep the secretariat alive. The last 3 years have seen no generation of money. Funds for carrying on the Secretariat activities for the next two years are earmarked. The New CHNRI Secretariat at IEO will receive USD 125,000 towards operations cost per year for next 2 years.

ii) FOLLOW-UP ON EXISTING MOUS - International Epidemiology Association (IEA): A MOU was signed between IEA and INCLEN in 2008. There is continuous attempt to scale up collaboration between INCLEN and IEA. In 2009 a workshop was organized for capacity building in India. INCLEN has been invited to the "World Congress of Epidemiology 2011" in Scotland, to submit a proposal for organizing the Plenary, Symposium and Workshop. In the Global Meeting due in August 2011, two plenaries will be presented, one on Governance and another on Disabilities. For the regional meeting in May 2010 at Colombo (Sri Lanka), AKN (President, IndiaCLEN), Tazin Jaffer (Member from Pakistan) RMP (INCLEN-IEO Coordinator), Shah Ibrahim (PHFI) and Damien (From Ethiopia) will present the plenary on governance of public health systems and an INCLEN symposium highlighting network activities. Also Dr. Shah Ibrahim will be delivering a talk in a symposium as well as one workshop.

**iii) IN PROGRESS - INDEPTH: AH** commented that INDEPTH was started in Africa and expanded to other continents. They receive funding for setting up demographic surveillance sites that enable further research on issues of major public health relevance. INDEPTH works through some universities where INCLEN-Africa has CEU presence (e.g. Ifakara University in Tanzania, Wits University in S.Africa.)

INCLEN seeks partnership to expand its portfolio of activities particularly in INCLEN-Africa. INCLEN will benefit from this partnership by gaining access to INDEPTH"s demographic surveillance sites, where specific research questions can be posed and capacity building undertaken particularly through learning-by-doing strategy. INDEPTH network has the opportunity to leverage on our strength of quality, research methodology training and university affiliation. INDEPTH may introduce some Doctoral programs or Capacity Building programs in its sites, and it will need support of trained faculty, in which case having linkages with CEU universities will be highly beneficial.

To discuss finer points of the partnership, a series of teleconferences with INDEPTH have taken place in the last six months. NKA attended the Annual INDEPTH meeting in Pune (India) in September 2009. In May 2010, to formalize the partnership there is a face-face meeting scheduled between Osman Sankoh (INDEPTH, Executive Director), Dr Bernhards Ogutu (Chief Program Officer, Malaria Clinical Trial Alliance Project in Africa), AH, 2 officials from INCLEN-Africa, NKA and MKD from IEO. The Board encouraged IEO and NKA to follow up on this agreement with INDEPTH. In preparation for the May 2010 meeting, the Board suggested having background ready for how CEUs could use this opportunity. Two strategies were suggested: 1. some CEUs Investigators could develop proposals and generate resources to work at INDEPTH site; and 2. they could become part of the ongoing research programs. There was significant discussion about how to involve CEUs that are already strong in Asia and Africa. INCLEN-Asia, INCLEN-Africa and IndiaCLEN will evaluate how they ensure a higher level of involvement in the INDEPTH network.

#### iv) EVOLVING PARTNERSHIPS:

- **1. Public Health Foundation of India (PHFI) :** PHFI has shown renewed interest in a MOU with INCLEN. (Anticipated formalization-March 2010). During last review of this MOU in 2007, it was acceptable by the Board in principle. The MOU will be a tripartite agreement between INCLEN, IndiaCLEN and PHFI. This is an India-centric program. Broad framework of the MOU is as follows: Working jointly on research proposals, with the government, in training programs, IndiaCLEN to provide sites for practicum of PHFI students and vice-versa and IndiaCLEN faculty to be co-opted as adjunct faculty in PHFI and work together. The Board commended the prospective partnership.
- **2.Duke University:** Duke University has a unique research coaching program called Research on Research (R-O-R). The secretariat is in Singapore and hence the concentration of activities there. The program's aim is to effectively train researchers in translating research information into high-impact scientific publications and developing new proposals. A structured local and distant mentoring arrangement is in place for this program. For some of its activities a charge is levied, though web-based modules and activities are available free of cost online. IndiaCLEN has been interested in similar elearning mechanisms, e-mentoring, virtual campus concepts, and capacity building initiatives. This is a way to build on each other's strength. Thus between December 2009 to February 2010, a series of teleconferences and a meeting with Dr. Ricardo (Director of "Research-On Research") in December 2009 was organized to further the discussions.

Duke University is interested in partnering with INCLEN to: 1. Compare a group of CLEN researchers trained as a part of the original capacity building program of INCLEN, with a similarly located non-trained faculty and compare their research output as an impact assessment. A proposal has been submitted for evaluation. 2. To be associated with E-learning being developed as part of INCLEN's capacity building initiatives.

The BOT members had some reservations about the whole initiative and suggested that another proposal be submitted from "R-O-R", clearly outlining the objectives and limitations of such a study.

**3.** Institute of Genomics and Integrative Biotechnology (IGIB): IGIB is a premier Indian institute under Council of Scientific and Industrial Research (CSIR), engaged in research of national importance in genomics, molecular medicine, bioinformatics, proteomics and environmental biotechnology. It is one of the finest genetics institutions in whole of the developing world and one of the pioneers in Epigenome study. Also as per CSIR mandate they can participate in partnerships beyond Indian borders. As INCLEN"s major thrust is in LMICs, Africa and other parts of Asia, we can expand this partnership to other parts of the world subsequently. Also as CSIR is a funding agency, the relationship could be beneficial in future endeavors. MOU with IGIB is important in the context of the partnership in the research initiative on Childhood Obesity. It is also a partner in Vitamin B12 deficiency proposal, wherein it supports epigenetic and molecular biology investigations.

The BOT endorsed the partnership and gave its approval to go ahead with the MOU.

**4. Jamia Millia Islamia University(New Delhi):** Jamia Milia Islamia is a premier Institute with specific research focus on Applied Science and Humanities, Biosciences, Biotechnology, Center for Interdisciplinary Research in Basic Sciences, Psychology, GIS (Geographic Informatics Systems). Their GIS (Geography Department) especially is one of the finest in India. They are potential partners in the Childhood Obesity and Brain to Society surveillance project, where they will provide support in investigating and integrating GIS information with data related to other components of the Obesity project. JMI has a direct relationship with ISRO (Indian Space Research Organization), which has access to satellite based imaging facilities. Thus this is a strategic partnership. The next phase of Childhood Obesity project would greatly benefit from access to this technology via expanded coverage at a minimized cost rather than with any other organization in the developed world.

The BOT endorsed the partnership and approved of it.

#### v) GUIDELINES TO DEVELOP NEW PARTNERSHIPS:

A project on Steroids in Cardiac Surgery (SIRS) trial was to be carried out in collaboration with McMaster University. INCLEN had to withdraw from this, as the MOU with McMaster University was altered at an advanced stage. The principal investigator at McMaster University insisted on the reserving the ownership of all data. This was unacceptable to INCLEN investigators. This issue was extensively discussed. For SIRs project IEO had been directly interacting with the McMaster University and the principal investigator.

The BOT suggested that it is desirable for the CLEN Secretariat to be involved in such inter-CLEN partnership endeavors. The Board suggested drafting an institutional policy on data sharing to formalize INCLEN"s policy on data ownership, sharing, access and application. CanUSACLEN was advised to assist in this endeavor. To aid in this, **DH** suggested referring to the Centre for Global Health Research (www.cghr.com). CGHR has developed a partnership assessment tool including data sharing and various forms of collaboration. **AH** offered to share INCLEN-Africa"s document developed on partnership, sharing and confidentiality.

#### **WEBSITE: DS** presented the renewed website and the Network Directory :

Phase 1 of website updation has been completed and Phase 2 has a deadline of 15<sup>th</sup> April 2001. There are 4 main objectives of Website renewal:

- **1.** To enhance overall look and appeal: The website will sport a sophisticated, mature and interactive feel. "The Network effect" will be depicted via a collage of member"s photos and a photo-video gallery.
- **2.** To enrich member experience and interest, new features added will be: "Become a Member today!" in Listserve, Alerts on Newsletters/Conferences/Workshops/Jobs, Feedback on SOPs/Minutes of Meetings and Research articles (Restricted access to BOT, and other identified members.), Annual CLEN Reports (2005-2010), Generic INCLEN presentation for use by members, Google Map to locate IEO, Site Map
- **3.** To expand features for research purposes, new features added are: Biosketches of IEO Research Staff, Abstracts / Publications of INCLEN Studies, Network member publications, Virtual Library of teaching/learning materials, List of priority research questions, Video Gallery, Donate Now feature, Blogging feature.
- **4.** Search Engine Optimization (SEO): To ensure INCLEN features prominently in web searches and Hit rates increase substantially from current 80-100 hits per day.

Some suggestions were made by **SS** for increasing the site hit rate: Various sample size calculators could be included on the site, or including a list of selected journals with high impact factor with closed/ open access, or by uploading INCLEN trainings and research information.

AH expressed concern over public access to Annual CLEN reports via the website. Various options for this issue suggested were: Restrict access to only Board members; or restrict access to only Board members in Phase I but by Phase II remove restriction; else the CLENs may provide a summary of Annual Report to upload on the public domain; or CLENs may mark out restricted areas in reports e.g. problems and challenges. The Board however felt that transparency in reporting was important as INCLEN is an International organization and it would also be useful to maintain Annual Reports in public domain for open viewing by donor agencies. It was noted that formalization of the reporting format of CLEN Reports was required.

**Network Directory Update :** In its annual update of 3000 plus contacts, 650 plus are already updated, as on the day of this BOT Meeting. The Network Directory Updation has a deadline of 15<sup>th</sup> April 2010. There is need for further support from CLENs in this endeavor. The method for using the Network Directory was explained in detail by **NKA** and **MKD**.

#### **REGIONAL CLEN REPORTS:**

**1.CanUSACLEN:** CanUSACLEN held its 5<sup>th</sup> regional meeting in Kingston, Jamaica on February 19-20, 2009. The addition of the University of West Indies as a CEU to the CLEN was announced here. The Caribbean region is in dire need of skills in the area of Epidemiology and shall be taking a leadership role for the region. CanUSACLEN shall be providing support to achieve this objective. In terms of proposed activities, a 3-year, multi-CLEN, joint research proposal (CanUSACLEN, INCLEN-Africa, INCLEN-Asia, LatinCLEN, India CLEN) on "The World Shake Project" (Shaking Baby Syndrome) has been submitted to National Institute of Child Health and Development (NICHD). Several lead scientists from CanUSACLEN are supporting and providing technical assistance to strengthen capacity in IndiaCLEN and LatinCLEN. For supporting and catalyzing activities at the proposed IIGH, **LS** suggested that experienced and founder members of INCLEN from the CLEN (Comprising of 8 CEUs/CERTCs-Three in Canada and five in the USA), could be the personnel of choice.

**2.** ChinaCLEN: ChinaCLEN comprises of 8 CEUs and 2 R-CERTCs. ChinaCLEN has been able to establish close working relationship with the Ministry of Science and Technology of People"s Republic of China. The department has accepted the ChinaCLEN report "Development Strategy for Clinical Research" and the area of high quality of clinical research will be covered by "China Key Projects in the National Science and Technology Pillar Program" during the next five years. This will include six national projects of major clinical significance. In addition, ChinaCLEN members have received grants from several national agencies: National Program for Science and Technology Development "973" on Chinese traditional medicine, National Fund for Distinguished Young Scholars, National Nature Science Fund and Chinese Centres for Disease Control and Prevention.

ChinaCLEN is also trying to forge closer cooperation with International Organizations. "Erasmus-Fudan-ChinaCLEN" Joint Program is an ongoing prospective cohort study. Similarly an international cohort study has started under Norway-Sino agreement on Chinese Traditional Medicine. Prof. Jiyao Wang has contributed an article "Evidence-based medicine in China" to Lancet; contributions by ChinaCLEN and INCLEN are prominently mentioned in this article. Clinical Epidemiology is now a part of the curriculum in undergraduate programs, graduate programs and postgraduate programs in 6 universities in China. The immense success of the training program on "Clinical Epidemiology Continuing Education Program for Clinicians in Shanghai" was remarked upon as well. Through online distance education in 2009 ChinaCLEN has offered a variety of courses for over 100 clinicians in China. Some important events highlighted were: 20th Anniversary of ChinaCLEN (Oct.16-17, 2009), ChinaCLEN Board Meeting (Oct.2009), National workshop on Evidence-based Medicine & Clinical Practice (Oct.16-18, 2009), National workshop on Meta-Analysis and a National workshop on Clinical research method on TCM.

The 11th Bi-Annual Clinical Epidemiology Conference of China will be held in July 2010. A new membership application has been received on 8<sup>th</sup> February 2010 from Centre for Clinical Epidemiology and Evidence-Based Medicine of Second Military Medical University of China.

The scale of grant received by ChinaCLEN from the government has been in the vicinity of USD 1 mm. ChinaCLEN and Prof. Wang were commended on having a profound impact on research in China and giving greater visibility to INCLEN and the ChinaCLEN Network. The Board felt a strong sense of success and agreed that ChinaCLEN"s achievement needed to be shared with the Network and the world.

**3. RECIF-Euro MedCLEN:** A brief introduction was given about establishment and reformation of Euro-Mediterranean CLEN. The Linguistic rationale of the CLEN was remarked upon. Due to the CLEN"s founding structure, the English-speaking parts and a large part of Europe were not included.

Currently RECIF-EuroMedCLEN comprises of 4 CERTCs and 6 CEUs. RECIF-Euro MedCLEN was noted to be more formally linked with UNESCO now, with even a board representation. RECIF-Euro MedCLEN University Diploma trainings are imparted on Clinical Research (From idea to publication), on Medical Economics and on Ethics in Health. Each CEU/CERTC is promoting clinical research training for general practitioner teachers. A European Masters degree in Clinical Epidemiology and a Masters Degree in Ethics in Health & Philosophy is also being offered. Annual seminars were organized in Romania, Morocco (Marrakech), Algeria (Annaba). Student exchange programs in training and research in clinical epidemiology are being carried out between CEUs. Publications on clinical practice guidelines and on clinical research are in pipeline. RECIF-Euro MedCLEN expressed interest in undertaking study trials with China and India, particularly for Traditional Medicine.

Progress made between 2009-2010 was noted to be through advancement in stem cell therapy, clinical evaluation through therapeutic hydro-therapy and pharmaco-epi of trace elements, establishment of the European Network of Research Ethics Committee, a new masters degree in Medical Philosophy; and proposed French Global Conference on Ethics in Health to be held on 15 September 2010. The CLEN has been asked to create a new ethics committee for medical teaching, research and enhanced care.

Independent efforts of CEUs to survive and carry on with their activities was appreciated. It was noted that CEU members need protection in terms of time and funds to prosper and gain confidence to grow as network entities. There was discussion on the evaluation criteria for CEUs and CERTCs. These evaluations can be external or internal. The parameters for evaluation can include courses offered, faculty attracted, grants attracted and publications. To ensure fiscal health of the network, INCLEN needed to develop more international research in collaboration with other regions and attract bi-lateral and multilateral funds using the network. A more global outlook organization needed to be thought of without losing the long term vision. This will need to be kept in mind while INCLEN goes into the next phase of its strategic vision including setting up of IIGH. Hence the rationale behind IIGH needed to be shared widely with the CERTCs and CEUs so they may identify with it.

**4. INCLEN-Africa:** It was noted that the term of current Executive Secretariat Office of INCLEN-Africa ends in 2010 after which it will shift to an alternate location. The INCLEN-Africa Council comprises of two representatives from each of the 9 CEUs/CERTCs. Ifakara University and Wits University could be explored for the possibility of turning into Centers of Excellence in the context of proposed strategic plan for INCLEN and IIGH. INCLEN-Africa continues to be the main health research capacity builder in Africa. CEUs in each university are regarded as the main resource for training at undergraduate/ postgraduate level in research and clinical epidemiology. The University of Zimbabwe and University of Pretoria have applied for CERTC status. Makerere University, though not a CERTC, is undertaking considerable training independently. Masters and Ph.D level courses are imparted in University departments.

In upcoming projects, the WHO project of "Best Care Africa" was conceptualized by and driven by IEO in partnership with INCLEN-Africa secretariat. However the WHO secretariat also involved certain other European and African partners. INCLEN-Africa and IEO were made a minor partner by WHO and only USD 36000 out of a 2 million dollar project are proposed to be kept aside for INCLEN-Africa to conduct 2 workshops. Thus the Network was strongly urged to adopt primary roles in projects to the maximum extent possible. Also the African Organization for Research and Training in Africa (AORTIC) plans to develop a liver cancer working group within INCLEN-Africa at Suez Canal University. The INCLEN-Governance project is in the phase of data analysis and report writing. Several new research programs have started within CEUs. INCLEN-Africa was a key partner to Research program Consortium led by the INCLEN Trust entitled "Health for Development-A Strategic Road Map for Translating-Evidence to Action" a 6 country study in Africa and South Asia. The proposal for this was submitted to DFID but was

not accepted beyond the Letter Of Intent stage, now it will be refined and submitted for an upcoming RFA in June 2010.

University of Pretoria CEU has conducted multiple workshops in partnership with the pharmaceutical industry regarding evidence-based medicine. Makerere University CEU M.Sc. Program is now supported by the University. Other trainings carried out at the CEU level are on research methods, short courses/workshops in clinical epidemiology and biostatistics, Courses/workshops in health economics/ ethics and evidence based healthcare. Addis Ababa CEU is offering courses for Ph.D. and M.Sc. in Microbiology, Biomedical sciences and Nursing. Suez Canal University CEU is conducting a mentoring program. Workshops are being conducted over research protocol writing.

Wits University CEU has expanded capacity to include new faculty members from myriad specialities, and is offering many courses with the Johannesburg University that are much in demand. In 2009 their application for promotion to CERTC level has been accepted by the Africa Council, hence **AH** urged the Board to accept the same. Two applications were received from Aberdeen University and Botswana University and are under consideration for CEU status.

Some of the difficulties faced by INCLEN-Africa were discussed : The network in Africa was sensing a weakening of its strength and identity due to difficulty in collaborative work.

Also members of INCLEN-Africa see no value addition in routing projects via the Network and prefer to generate opportunities independently. There are additional issues of team-building and ownership among and between CEUs and lack of identification with INCLEN of CEU members which has magnified the CLEN"s problem of sustenance and resource generation. The difficulties of registering INCLEN-Africa as a regional NGO have already been highlighted.

Yet INCLEN-Africa's continuing active participation indicates their hope of a rebirth and opportunity to engage more actively with INCLEN. INCLEN-Africa intends to continue collaboration with IEO to develop and implement pertinent research proposals while expanding CEU member base. The Board suggested that one solution may be securing a multi-site grant. Another suggestion was increasing inter-CLEN collaboration if the area of research interest matched. AH was hopeful of the proposed strategic evolution of INCLEN bringing about more visible mutual benefits for all participants and thus being able to utilize the network better.

**5. IndiaCLEN:** In absence of **AKN**, the Board agreed that participants review the progress report themselves, and questions if any could be addressed to **AKN** later. Based on the progress report submitted by IndiaCLEN, the summary of annual report is presented hereunder:

IndiaCLEN has now 10 CEUs and one CERTC. In addition, IndiaCLEN has signed a MOU with four new institutions to establish CEUs with financial support from USAID under MCH-Star program. IndiaCLEN has an active IRB which meets biannually. One of the major USAID grant of IPHIDE under Country Research Program (CRA) ended on 30 September, 2009. This five-year grant was for almost USD 4 mn and resulted in several large nation-wide studies. Final report of the program was submitted to Boston University (Lead Organization administering the grant) and USAID-Washington office.

Some of the important studies accomplished under the program are: IndiaCLEN Neonatal Health Initiative, Clinical profile and outcome of MDR-TB in India, Baseline assessment of childhood health indicators in sixteen districts in preparation for the assessment of impact of IMNCI, Model injection Centre program, management of ARI with wheeze in childhood; and oral amoxicillin for the management of severe childhood pneumonia.

Since 2007, IndiaCLEN has participated as a key Star Supported Institution (SSI) under the USAID-MCH-STAR program. During 2009, on the request of IndiaCLEN, MCH-Star commissioned a consultation with two renowned management consultancy firms for the Strategic planning of the organization. IndiaCLEN Governing Board has accepted the recommendations of this strategic planning report and is in the process of developing a roadmap for implementing the strategic plan. Workshops on policy analysis and advocacy, qualitative research methods and analysis, biostatistics and health economics were conducted across the country during 2009. To encourage and bring younger research leadership in the forefront of IndiaCLEN activities, IndiaCLEN has instituted awards for the Best Young Researcher and Best Protocol. During 2010-2011, major thrust of the organization will be on restructuring and implementing the Strategic Plan.

6. INCLEN-Asia: 13 CEU s and 4 CERTCs are part of INCLEN-Asia network. The linguistic and demographic variety of INCLEN-Asia was acknowledged as a challenge and an opportunity. Foundation for the Advancement of Clinical Epidemiology Inc. (FACE Inc.) is a registered not-for-profit organization that looks after fund management, financial statement maintenance, auditing and book-keeping for INCLEN-Asia. Registration of FACE in the Philippines had been easier as members were locals and also financially they were relatively more viable. On the other hand, if INCLEN-Asia had tried to register in another member country, it could have been a tedious and expensive task. Thus FACE could be the registered organization for the INCLEN-Asia network. INCLEN-Asia"s Self Instructional Modules are being used in graduate courses and workshops in biostatistics and clinical economics and EBM workshops. Rapid strides are being made in education and training through University Masters degrees in Clinical Epidemiology, training in research methods, clinical epidemiology, EBM and other related disciplines. CCEB in Australia is offering a Master of Public Health Program in 2010. CEUs like De la Salle, UST, CIM are offering training in research protocol/ program development, critical appraisal and EBM to professional healthcare organizations. Gadjah Mada University, Aga Khan University, Hanoi Medical University (HMU) have been very active in offering a multitude of education programs in clinical epidemiology and related fields, trainings, organizing international conferences and workshops. To further pursue their interests in research ethics, HMU may benefit by contacting RECIF-EuromedCLEN whose area of strength is in ethics.

In a process facilitated by IEO-Delhi, INCLEN-Asia participated in the Sendai Seminar in Japan (Tohoku University) organized by CEU Director, Prof. Naruo Uehara. Five INCLEN-Asia members and one IndiaCLEN member attended this three week seminar. Gadjah Mada CERTC agreed to be part of the Research Program Consortium led by The INCLEN Trust International. The letter of intent was submitted to DFID for consideration, and to be funded by DFID. Clinical Research Centre (CRC), the clinical research arm of the Ministry of Health in Malaysia was created to support implementation of policies and guidelines for conducting clinical trials, and registering them in publicly accessible research registers. Thus CRC might be suitable for becoming a comprehensive trial registry for the INCLEN network. Other significant activities for INCLEN-Asia were: Philippines CLEN celebrating 25 years of Clinical Epidemiology. A convention on "Contributing Evidence Towards Optimum Health care and Equity; an ACTA Medica Philippina publication dedicated to Clinical Epidemiology are some other important events.

The problems highlighted were: The need for regeneration of INCLEN-Asia. Also no financial support was received from IEO in 2008 and 2009. However, **SC** explained that as INCLEN-Asia and LatinCLEN had not applied before financial year end, they were unable to secure the financial support that had infact been pre-approved by the Board.

**7. LatinCLEN:** LatinCLEN comprises of 16 CERTCs and CEUs located in 9 countries. Tenure of LatinCLEN was extended for one year in the eleventh LatinCLEN Congress, held on June 2009. New executive committee election is due in March-April 2010. The eleventh LatinCLEN meeting was held in

Bogota, Columbia in partnership with the Ibero-american Cochrane meeting and was attended by 109 members.

At the regional level, no new inter-country projects have been initiated. A letter of intent for the "World Shake" has been submitted to NIH in partnership with CanUSACLEN, INCLEN Africa and IndiaCLEN. In the arena of capacity building and training, the 5th consecutive cohort of students is undergoing the elearning Master Program in Clinical Epidemiology in Temuco University (Chile) and Javeriana University (Colombia). UFRO-Temuco (Chile) coordinates this regional training program. An evaluation of the pedagogic model and student satisfaction has been performed. CERTCs and CEUs in Chile are working closely with the Ministry of Health for capacity building initiatives and providing assistance in policy-making. A request from the health ministry was received for a cost-benefit analysis on the burden of new disease on community. Guidelines for diagnosis are also being developed. The project completes on March 2010. The new health minister in Chile is a former LatinCLEN affiliate, and an epidemiologist trained at McMaster University. LatinCLEN is trying to develop a MOU with PAHO for building capacity in operational research protocol development and data management for health personnel in the region.

Some important meetings to be held are: Next meeting with the Ibero-american Cochrane collaboration network and the LatinCLEN in Peru in 2011. The IX Congress of Ibero-american Cochrane Collaboration Network will be held in May 2010. Two new CEU applications have also been received and are under consideration of the Executive Committee.

SM shared the broad outline and evaluation of the e-learning based M.Sc. Clinical Epidemiology program of LatinCLEN. The broad outline of this evaluation was to strive for accreditation. The model is tutorbased and based on reflexive learning. Prior to launch of the program, an international gap analysis was done. Seventy percent of the individuals (i.e. 126 out of 180) contacted during the survey agreed that the e-learning mode of education would be effective for training in Clinical epidemiology, Research Design Methodology, and Biostatistics. This course currently has 4 semesters, with core and elective courses and a thesis submission. The course faculty originates from CEUs and CERTCs and is trained for tutoring by INCLEN; first in a face-to-face mode and then through the distance mode. The initial funding for this was received from INCLEN. The degree is granted by UFRO Public University. The course fee for the twoyear course is USD 8000. The class comprises of 15-16 eligible students from diverse countries. Most of the class is employed and hence finds the e-learning mode convenient. One tutor is responsible for mentoring ten students. Details were shared on how the course curriculum was developed. Formally no competencies had been developed. Development of the curriculum involved faculty from CanUSACLEN as well. The course uses a free and sophisticated, web-based platform-, Moodle" to familiarize students in the first four weeks. Teaching takes place via presentations, readings, daily web contact, with no "Faceto-Face" contact. Evaluation is done through grading of timely assignments. These courses are currently available in Spanish language only. The Board suggested that the English translations of these courses could be tested to enable pervasive usage.

The evaluation of the training program revealed overall satisfaction with e-learning mode in terms of content, method, feedback, interaction and resources. This mode was found to be very satisfying for Clinical Epidemiology and Research Design Methods courses. For Biostatistics course the level of satisfaction was low. Biostatistics required more interactive discussions and problem-solving. Performance was better by students who were in the age group of forty years and above, who had over fifteen years of experience and preferably had some prior research experience.

#### **NEW CEU/CERTC APPLICATIONS:**

- 1. Wits University of the Witwatersrand: In 2009, INCLEN-Africa Council approved up gradation from CEU to CERTC status for Wits University. Pretoria and Wits University now collaborate on various courses, training programs and academic degrees. **AH** urged the Board to accept this application. Motion to approve was moved by **JS** and was seconded by **FC**.
- 2. The Second Military Medical University: This University in China has applied for CEU status. Their staff has rich expertise of Epidemiologists, Biostatisticians, Clinicians, Health Economists, Clinical epidemiologists and Statisticians. Their application has been approved by ChinaCLEN. The Board accepted the application.
- **3.** The Koirala Institute of Health Sciences: They have applied for CEU status. Expertise of their staff was noted. **MED** was asked to discuss the application with the INCLEN-Asia governing board. The BOT approved this application, pending confirmation from INCLEN-Asia in two weeks time.
- 4. Japan University: The formal acceptance of Japan University application for CEU status was to be decided by the governing body of INCLEN-Asia. The status of the application is to be intimated to the Board of the final decision.
- 5. IndiaCLEN has signed MOUs with four new CEUs since 2009, with USAID assistance.

**SM** was asked to share with the Board, the criteria for CERTC accreditation with IEO. The Board agreed, henceforth new CEU acceptances needed approval from the particular CLEN, and the Board need only be informed of the outcome.

#### **BOT DECISIONS:**

- **1. Registration of CLENs as legal entities :** Board discussed on this topic on Day 1 of the Meeting. (Details on Page 2)
- **2. Inclusion of NGOs as network members : SK** elaborated on this issue through a presentation and thereafter the Board discussed it in detail. (Details on Page 3)
- **3. New Board Of Trustee Members :** Manuel Emerson Donaldo (**MED**), upcoming President of INCLEN-Asia and Professor Bob Black, Chair of CHNRI were formally welcomed as new Board Of Trustees member of INCLEN Trust International. This was ratified by **JS** and seconded by **LS**.

#### ANNUAL REVIEW OF LEGAL AND ADMINISTRATIVE MATTERS:

- 1. Legal & Administrative Matters: Registrations have been applied for and certifications awaited on Permanent Registration under FCRA (Foreign Contribution Remittance Act), Exemption under 80G of Income Tax Act of India, Exemption under 35(1) of IT Act of India and Recognition as Scientific and Industrial Research Organization (SIRO). In other legal matters, a supplementary Trust Deed has been registered to document change in address and membership. BOT was informed about a court case filed in September 2008 by R.D. Ramnath & Company (Owner of previous IEO office premises) claiming enhanced rent and damages for overstaying. IEO is contesting the case in Delhi court.
- **2. Standard Operating Procedures :** The Board was informed of the revisions being made in the SOPs of the Trust as per the Laws of the Land. The base for these revisions is the external evaluations carried out by two well-reputed consultancies for IndiaCLEN and INCLEN. The revised SOPs especially focus on efficient management of grants received from diverse funding sources. The SOPs are to be divided into 5 divisions: Governance, Grant management, Finance, Human resource, Forms and formats. Latest updates in operating procedures will be explained via these SOPs. Draft SOPs will be circulated to Board members and approval sought before implementation.

- **3. The Financial Calendar :** For INCLEN Delhi and Philadelphia offices Financial Calendar 2009-10 was reviewed. The various tasks laid out in the financial year, their deadlines and important remarks regarding their status were presented to the Board.
- **4. Setting up of INCLEN Trust Development Fund :** This was proposed to optimally utilize funds and balance overheads of completed projects/programs. These funds shall be spent for core activities of the organization and other activities considered essential to further the mission and vision of the Trust. This would also include interest earned thereof, unspent overheads, surpluses of income & expenditure account, and donations received. It was indicated by board members that some funding agencies might ask for prior approval to transfer funds to such an account. The Board suggested rewording and calling this fund-,,The Executive Director"s Discretionary Fund" or ,,The INCLEN Overheads Account" or ,,INCLEN Trust Core Fund". To minimize chances of donors considering this as overspending and seeking reimbursement, the Board suggested charging this amount to ,,Services and Overheads". Another suggestion was, INCLEN seeking fixed cost contracts as far as possible to avoid limitations on usage of unspent funds. It was agreed that as per mandate the Executive Director would have the autonomy to use this fund. The fund management shall be reported to the Executive and Finance committee. The Board unanimously approved the creation of a new account for this purpose.
- **5.Accrual Method of Accounting :** IEO-Delhi proposed to shift form Cash to Accrual method of accounting w.e.f. April 1, 2010. The Board reviewed and accepted the proposal unanimously.
- **6.Tipping :** The Board was informed that INCLEN Inc (Philadelphia) status as "Non-Profit, Public Charity Organization" under 501C(3) Act of IRS (US Tax Authority), would "tip-over" in 2010-11 due to increased grants from private foundations (BMGF primarily) and diminished grants from government and other public organizations. Thus private donations made henceforth to INCLEN Inc. may no longer be tax exempt. INCLEN Inc. did not receive private donations in the last ten years, and has been primarily been dependent on government funding; hence the situation is not of a grave concern. This "tipping over" could be slightly delayed and even be reversed by receiving a significant government grant. The Board was assured of INCLEN"s functionality and preservation of same status with the public foundations/government even incase "Tipping-Over" occurs.

#### **FINANCIAL MATTERS:**

- **1. Financial status : SC** presented the Financial Report for year ending 31<sup>st</sup> March 2010. All categories of expenditure were noted to be under spent. To minimize corpus spends, the larger studies had been structured for self-funding. The "Best Prospects" category had unspent funds due to non-initiation and cross subsidy of certain large, priority projects planned. Many CLENs were unable to take advantage of funds set aside for their usage. BOT was able to use 98 % of funds allocated for its use. Operations expenditure incurred in running both the IEO Delhi and IEO-Philadelphia was noted to have been significantly curtailed. The cash balance availability with the Trust since 2001 was traced and it was noted to have significantly improved, especially since FY 2009-10 after reaching an all-time low in 2008-
- 9. Enough cross subsidies were used to support the corpus. Lastly, the last 5 years under the current Executive director"s tenure were traced and the process in which financial turnaround was achieved was discussed. Cross-subsidizing organizational functioning through projects operated from IEO was one of the key strategies in this process.
- **2. Audit Reports :** The Board was informed of the review of audits by the Finance and Executive Committee. Operations of the INCLEN Trust International, Inc. (Philadelphia) have formally ceased. It was noted that no issues were raised during audits of INCLEN Trust International (New Delhi). Returns were filed on a Cash basis. All necessary permissions to operate with foreign funds were detained for INCLEN Trusts" activities in India. At present approximately USD 50,000 are available in INCLEN Trust International bank account in Delhi. Any possible pay out in the ongoing court case against the trust, though unplanned for, would imply a maximum of 50,000 USD pay out. The INCLEN Inc. audit reported delays in submitting the FY 2008 audit requirements and delays in billings for existing grants. BOT was kept informed of the difficulties with the previous Finance Officer at IEO-Philadelphia and the reasons

for audit delays. However in the current scenario all deficiencies have been taken care of, appropriate corrective actions taken and an unqualified opinion obtained from the auditors. The Audit reports of 2007-08 and 2008-09 have been submitted to appropriate authorities in USA. The expense categories of FY 2009 submitted were reviewed. The categories of "Capacity Building" and "Admin and Gen." expenses were noted to have dwindled. Significant transactions for FY 2009 were explained through the status of federal grants received, revenues, expenses incurred, net assets and status of cash balance. **NKA** and **SC** were commended for their significant efforts.

**3.Membership Fee Issue**: The Board approved the proposal for CLENs to receive and retain the membership fee of USD 100 for enrolling new CEUs and CERTCs in their region, to minimize the loss during bank transactions.

**4.Investment Policy:** The Board was requested to review its earlier decision to disallow any kind of investments. With the Trust having relatively predictable cash inflow and outflow for its activities, in the dynamic global economy context, safe investment options could be explored while maximizing returns. The Executive Director and his team will develop an Investment Policy suitable to the laws of the land and mission of INCLEN Trust. The Board approved the creation of such an Investment Policy that carefully reported to funding agencies. The Finance and Executive Committee would supervise its management.

#### **WORKPLAN FOR YEAR 2010-11:**

#### STRATEGIC MATTERS - REINVENTING INCLEN:

**NKA** made a presentation on the proposed strategic direction for INCLEN as a network and as an organization, to try and get the Board"s wisdom on how to move forward to the next stage of INCLEN"s evolution.

There was extensive discussion on the proposed "INCLEN-Reinvention 2010" strategy document. Infact almost fifty percent of the total BOT meeting time was spent on discussion on this important issue. Broadly the comments and discussions can be categorized into three parts:

- 1. Relevance and benefits of the Reinvention Plan.
- 2. Concerns
- 3. Suggestions to carry forward the Strategy Workplan.

#### 1. Relevance and benefits of the Reinvention Plan:

BOT was unanimous that INCLEN Strategy proposal was timely and all agreed in principle to move forward with the concept. It was acknowledged that as most INCLEN members were busy clinicians, the framework proposed would provide opportunity to conceptualize and develop large multi-centric, multi-country studies testing and execution using the IIGH platform. The strategy would make available more INCLEN-branded studies to the global health scenario. The idea of working with Universities and twinning with PhD program was appreciated. Proposal to have global health as the front of the proposed strategy was agreed upon by BOT because this would give INCLEN the "early-mover advantage" from scientific, political and economic perspectives.

Finally, it was acknowledged that IIGH holds potential to take the current as well as future INCLEN researchers onto global leadership. An important point made was that institutions and universities never die. The proposed strategy would also have high potential to become a resource generation centre for INCLEN to survive, thrive and move forward.

#### 2. Concerns:

There were two major concerns; namely, INCLEN activities becoming more India-centric and weakening of INCLEN network and regional CLENs.

- The INCLEN network and its relevance appeared to have been subdued in the proposed framework.

- A certain amount of difficulty was perceived in understanding the legal and administrative structure within the overall framework of global INCLEN and regional CLEN networks.
- A threat being perceived was that at some time the primary INCLEN network might be dissolved.
- A concern was raised about IIGH competing with regional CLENs for the same pot of donor resources.
- Another concern was about articulating and communicating a consistent message about the "Strategy to Reinvent INCLEN". It was agreed that this will require detailed discussions, finalization of the document and subsequently inviting dialogue with CLEN-CEUs/CERTCs. Overall the view was to maintain the INCLEN network as an entity, intact at all times. Another observation that clearly emerged was that intense loyalty of INCLEN alumni exists for the network even in its tough times.

### 3. Suggestions to carry forward the Strategy Workplan:

It was agreed that the document and presentation were to be modified and prepared so as to make it less threatening and incorporate the above-mentioned concerns. **LS** agreed to work with **NKA** to modify the document. It was noted that the strategy would need wide ownership and acceptance. Hence the document would be discussed through teleconference with CEUs/CERTCs Directors (Board of Directors). The process would be coordinated by regional CLEN secretariats. The strategy document is also to be also shared with some of the founding fathers of INCLEN to get their feedback.

Some of the suggestions for IEO in preparing the revised workplan were

- : -The workplan should have synergy with the vision of INCLEN. -Relationship between IEO and proposed IIGH should be clarified. -IIGH should be identified as an initiative of global INCLEN program.
- -As IIGH establishes itself into a successful structure in the future, satellite campuses across CLENs may also be set up.
- -Mechanisms of faculty appointment, sabbatical or secondment conditions and career paths of the faculty required some more clarifications.
- -The structure and function of IIGH would be flexible and bereft of bureaucratic barriers, normally experienced in university structures.
- -Centers of Excellence could be better named as "INCLEN Centres of Global Health" (ICGH), for carrying out community-based studies and contributing to research capacity building through a
- "University Without Boundaries" philosophy. Such centres would be spread across CLENs. -
- "Learning-By-Doing" health research capacity building program could be better reflected within the strategy document.
- -IIGH can have an external scientific advisory group to guide, counsel and monitor its activities.

Overall BOT strongly endorsed and affirmed its support for the strategic direction and agreed to carry it forward, to truly reinvent INCLEN.

**Other matters:** The issue of CLEN registration needed immediate attention, especially by INCLEN-Asia and INCLEN-Africa. For this purpose IEO shall make USD 2500 available to each CLEN requiring registration. As indicated during past two years, CLENs were encouraged to avail funds for new projects development that are multi-country and within or between CLENs; USD 2500 for responding to Letter of Intent and USD 5000 for preparing the full proposal.

The BOT teleconference shall be scheduled in June 2010, and later on as per need, to discuss and finalize the Strategic plan for INCLEN. Two more Finance and Executive Committee teleconferences are scheduled for September and December 2010.

#### **BUDGET:**

Allocations have been made for overall expenditure, capacity development, new program development and regionalization. Other allocations proposed are for fundraising, marketing, public relations, best

prospects, BOT and executive office expenses. Overall cash requirements shall be met from internal funding and from project cross subsidies, overheads from BMGF, CHNRI, and NIH.

As per Indian Income Tax Laws of Government of India, to maintain status as a Charitable Trust, INCLEN is required to undertake community service e.g. health camps and similar activities in India. USD 20,000 have been set aside for this. The overall revenue and Expenditure situation and available balance as on 31<sup>st</sup> March 2010 were discussed.

For the core operations of CLEN offices at INCLEN-Africa, INCLEN-Asia, LatinCLEN and ChinaCLEN funds available shall be at the rate of USD 2,500 per CLEN for the year. The Board expressed hope for higher fund availability for CLENs in the coming years as the financial situation improves. In addition, CLENs were encouraged to generate own funds as well, particularly with the availability of seed funds to develop new projects. In conclusion **NKA** reiterated that INCLEN's strength was its Network and that the all important effort was to create a strong global INCLEN. The BOT unanimously approved the budget.

## **BOARD RESOLUTIONS:** The Board reviewed and approved the following resolutions:

S.No.	Board Resolution	Proposed by	Seconded by
1	Authorizing Executive Director to appoint Amper Politziner &	AH	MED
	Mattia, LLP as Statutory Auditor for FY 2009-10 on behalf of		
	INCLEN Inc.		
2	Authorizing Executive Director to invest available funds	AH	DH
	according to the laws of the land in order to maximize return on		
	investment while maintaining safety and required liquidity on		
	behalf of INCLEN Inc. and The INCLEN Trust International.		
3	Authorizing Executive Director for switching over to Accrual	JS	AH
	system of accounting w.e.f. 1 <sup>st</sup> April 2010 on behalf of The		
	INCLEN Trust International		
3	Authorizing Executive Director for setting up "INCLEN Trust	FC	JS
	Core Account" fund, to be spent using discretion for furthering		
	the mission and vision of the INCLEN Trust International and		
	to open a separate bank account in the Standard Chartered bank		
	to manage the fund.	~ · ·	77.0
4	Authorizing Executive Director to enter into any	SM	FC
	contract/agreement to purchase/hire/lease of additional office		
	space on behalf of The INCLEN Trust International and to sign		
	all the related documents pertaining to that contract/agreement		
	on behalf of the Trust	CM	MED
5	Authorizing Executive Director to appoint Kedar Nath	SM	MED
	Tripathy, advocate as Legal Advisor for the financial years 2009-10 and 2010-11on behalf of The INCLEN Trust		
	International and to represent the Trust in the courts of laws on behalf of the Trust.		
6		AH	MED
0	Authorizing Executive Director to appoint V.Sankar Aiyar & Company as Statutory Auditor for the financial year 2009-10 on	АП	MED
	behalf of The INCLEN Trust International		
	Delian of the inclein trust international		

The BOT meeting 2010 ended with thanks to the Chair of BOT and gratitude expressed to all CLEN representatives for their presence and active participation.