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Clinical Research Training and Capacity Building for Prevention and Control of Non Communicable Diseases: A Programme in India

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Abstract

Background: Non-communicable diseases (NCDs), a term which includes diabetes, cardiovascular disease, cancers, chronic respiratory diseases, and mental illness, are now the major cause of death in India and thus represent an important health care and economic threat to India. There is an urgent need for enhanced clinical research training and capacity building in NCD prevention and control in India.

Methods: Described herein is a multi-pronged approach funded in part by the US NIH Fogarty International Center, which was initiated in 2001 to train Indian present and future scientists/ doctors in NCD prevention and control. Approaches used included annual National seminars, intensive training courses, in-house workshops, short-term training sessions in the US and monthly video conferences.

Results: From 2001-2016, 3,650 undergraduate, post graduate and medical college faculty from medical colleges and institutes from almost all states in India and several neighbouring countries

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participated in the seminars and other capacity building workshops held at the Madras Diabetes Research Foundation, Chennai and at six other medical colleges; 883 delegates participated in the in-house workshops, 463 in the intensive interactive sessions; 244 in workshops on advanced techniques in genomics; and 37 in short term training sessions held in the US.

Conclusion: Through this unique capacity building programme, more than 5,000 individuals representing faculty and students from various medical colleges and research institutes across, and beyond, India, underwent training in the prevention and control of NCD's.

Keywords

Non-communicable Diseases; clinical research training; capacity building; prevention; India

Important issues for a training programme are a compelling need plus the availability of a suitable training model. Early in the 21st century, we faced this issue in the context of non-communicable diseases (NCDs) in India. The need was, and continues to be, compelling since the prevalence and incidence of diabetes and other NCDs are increasing dramatically in India—and in many other Lower Middle Income Countries (LMICs). Further, the number of medical colleges in India has grown very substantially in the past 10 years from less than 200 to now more than 350, with this growth expected to continue. Importantly, each post graduate trainee is required to complete a research project so that these colleges are required to undertake much more research than had previously been the case. Altogether, this represents several hundred new research projects each year. This is both an opportunity and a challenge since this process will certainly generate much larger numbers of competent researchers than have previously been available but the current training demands are very high. This mixture of the burgeoning burden of NCDs and new medical colleges with both new faculty and a mandate to do more research clearly signals that clinical research training and institutional capacity building were and continue to be an urgent need, which highlights the critical need for training programmes such as the one described herein.

The spread of NCDs including diabetes, cardiovascular disease, stroke, cancer, respiratory diseases and mental health presents a global crisis and is a major barrier to meeting the Millennium Development Goals [1]. Of the 57 million deaths that occurred globally in 2008, 36 million (almost two-thirds) were due to NCDs; the burden of these diseases is rising disproportionately among the populations of LMICs, with nearly 80% of NCD deaths (29 million) occurring in these countries in 2008 [2] and 60% of all deaths due to NCD in India [3].

With 69.2 million people with diabetes at present, projected to increase to 123.5 million by 2040 by the International Diabetes Federation (IDF), India ranks second in the world [4], and will soon hold the dubious distinction as the world leader in hypertension as well. In light of these compelling numbers, the government has initiated a national programme for Prevention and Control of Diabetes, Cardiovascular Diseases and Stroke [5]. NCDs are a critical health and development issue in India. A key component to realizing progress against NCDs in India is sufficient capacity at the national level to implement effective strategies for NCD prevention and control.

Against this background, the mission and focus was on the very critical issue of clinical research training and capacity building relevant to NCDs. Initially, it was planned to use the degree seeking model of sending delegates from India to the US for masters and doctoral degrees. It soon became apparent, however, that this strategy, for a variety of important reasons, was unlikely to have sufficient impact. Thus, the focus was on institutional capacity building and clinical research training in a manner that attempted to enhance and maximize on the scientists, educators and research and training institutions available in India. Initially, the Madras Diabetes Research Foundation (MDRF) in Chennai was targeted. For clinical research training, focus was on undergraduate and post graduate medical students, fellows, faculty and institute staff from across India with our National Seminar and Intensive Interactive Sessions.

This paper describes our strategy and the success for our programme, funded by the Fogarty International Center (FIC), National Institutes of Health, USA initially as the International Clinical, Operational and Health Services Research and Training Award (ICOHRTA) to the University of Alabama at Birmingham (UAB). Later, funding was from a FIC NCD LifeSpan Program award to Florida International University (FIU). MDRF, the major collaborator in India, UAB and the University of Minnesota (UMN) were involved from the outset.

Objectives of the Programme:

The main goal was to create awareness of the burgeoning NCD burden and to create a network of scientists across India equipped with useful skills for the prevention and control of NCDs. The specific objectives included:

1. To strengthen capacity of various institutions in India to conduct NCD research, to assess the magnitude of NCD's and to undertake interventions to reduce the burden of NCDs in their respective regions.
2. Support multidisciplinary research training in basic, genetic, clinical and implementation sciences (translational) in the field of NCDs
3. Integrate our efforts with others doing similar work to strengthen core research capacity in NCD prevention and control in India and neighbouring countries.

Initially, for capacity building, the focus was on enhancing the capabilities of MDRF; later these efforts were extended to additional institutions. Areas of training included research strategy, research methods, biostatistics, epidemiology, data management, laboratory methods, nutrition, genomics and genetics. Training activities focused on staff, investigators, teams, and students and included mostly seminars, workshops and individual or team work sessions. For institutions beyond MDRF, workshops and team work sessions that focused both on enhancing institutional capacity and on enhancing the skills of clinical research personnel were conducted. These included Karamsad Medical College, Anand (KMC-Anand), Gujarat; Kasturba Medical College, Manipal (KMC-Manipal), Karnataka; Gauhati Medical College (GMC), Guwahati, Assam; the Fakhrudhin Ali Ahmed Medical College (FAAMC), Barpeta, Assam; the Pondicherry Institute of Medical Sciences (PIMS), Pondicherry, Tamil Nadu, and the North Eastern Indira Gandhi Regional Institute of Health

and Medical Sciences (NEIGRIHMS), Shillong, Maghalaya [Figure 1]. Programmatic planning and overview of the programmes were undertaken with the help of the Internal Advisory Group (IAG). The IAG plays an important central role in trainee selection and programme activities and evaluation and also interact with the Training Advisory Group (TAG), which provided advice and assistance with trainee selection.

Methods

A multi-pronged approach was developed, implemented, and continuously refined to enhance clinical research training and capacity building, including the following components:

1. National Seminar –

A National Seminar on “Prevention and control of NCDs” conducted annually at MDRF, with faculty from the USA (UAB, FIU and UMN), MDRF and from across India for two and half days. Faculty were distinguished scientists and physicians from prestigious institutes and medical colleges, who were selected based on their expertise in the field of NCDs. The details of the programme were posted on the website and individuals were invited by sending flyers and emails to various academic institutions. All interested individuals were included in the programme. The programme included lectures on key current NCD epidemiology and prevention topics, research methods and ethics, study procedures, and how to translate research to practice and to the community. Workshops on the WHO STEPwise approach to Surveillance (STEPS) Programme and group assignments on designing prevention/intervention studies for different NCDs and their risk factors also have been included. Interactive workshops on research project development and implementation, ethics, and critical review of published articles to help the participants better understand and utilize the literature and organizing and preparing their articles were included as well.

2. Intensive interactive training Course –

In response to feedback from initial seminar participants, a 2.5 day intensive component was included in 2004. The objective was to enhance the ability of participants to conceptualize, design, implement, analyze, and critique various NCD research projects. Participants submitted proposals describing a research project either being planned, underway, or at the analysis stage. The research projects of the participants were graded by the faculty based on study design, analysis plan, quality and those consistent with the training objectives and selected for presentation. Initially the course was restricted to ten participants, but the sessions became so popular that two levels were created, core participants and observer participants, with about 30 presentations every year. These sessions represent a “train the trainer strategy,” whereby participants can pass on knowledge to others in their home institution.

3. In-House workshops –

These were primarily intended for MDRF faculty and staff, and include several days of training by the US team while they were at MDRF in February/March of each year. Included

were: 1) sessions with PhD students reviewing their thesis projects, 2) sessions with research staff on their ongoing and planned research, and 3) lectures and seminars for research staff and physicians covering topics ranging from updates on NCD epidemiology, research methods, updates on genomics and proteomics, a short course on biostatistics or recently published landmark studies.

4. National workshop for faculty -

Three half day faculty forums were conducted as another method in to strengthen NCD training in India. The workshop on the curricula for community medicine training in 2011 to ascertain the focus on NCDs. How teaching strategies relevant to NCDs can be enhanced, innovations and joint research projects shared and undertaken across colleges and regions in India was discussed. In the following year, a half a day workshop on “Prevention & Control of NCDs through nutrition” was organized, with faculty discussing solutions to specific problems related to NCDs from the nutrition point of view and major challenges/barriers on addressing NCDs. In 2013, a workshop on ‘Physical activity in India--Taking it Forward’ was organized. The purpose was to focus on ways to improve physical activity among adults and children in India. Various scenarios were identified such as the workplace, schools, colleges etc., which can be targeted for improvement in physical activity and recommendations to improve the current scenario in the various sectors were discussed. In each case, experts in the respective field were invited to MDRF for the sessions. These sessions were judged, while informative and helpful, not sufficiently effective for their continuation so they were dropped in favor of more time for the Intensive Interactive Sessions.

5. Seminars/Workshops at other institutions/medical colleges in India:

Given the success with the programme for MDRF, the programme was soon expanded to other institutions, with the first being a half-day workshop at KMC-Anand, Gujarat in 2009. Next was an initial workshop at KMC-Manipal, Karnataka followed by three annual research meets. These research meets also included faculty and students from other local medical colleges, especially from the Mangalore campus. These workshops focused on guiding participants in research methodology, including study design, biostatistics and data management.. The meetings were organized with a special focus on undergraduates and postgraduates in general and community medicine but also included nursing, physiotherapy and PhD students.

Specifically at the request of the Indian Council of Medical Research, a focus was added on the North East and included the GMC in Guwahati, Assam; the FAAMC in Barpeta, Assam; and NEIGRIHMS in Shillong, Maghalaya. The GMC workshops included faculty from across the college and also from other local colleges. The half-day workshop at FAAMC was the first research seminar/workshop this new college had held. Attending were the college leadership, faculty and the initial class of first year medical students. The sessions at NEIGRIHMS included presentations on several topics relevant to NCD research methodology and was attended by the Director, faculty, staff, students and post graduates for NEIGRIHMS and other local colleges.

6. Short-term training in the US –

This component offered intensive short term training in the US to staff of MDRF and collaborating institutions in key areas of research to enhance knowledge and fill existing gaps in skills. The trainees were selected from various departments at MDRF, including Epidemiology, Nutrition, Biostatistics, Genetics, Biochemistry, clinical trials and cell and molecular biology. The training typically was for four to six weeks and was conducted at different institutions across the US. As a part of the training, all participants are required to complete the online University of Miami Collaborative Institutional Training Initiative (CITI) course on the responsible conduct of research. For some years, the training was conducted during September so that trainees on site at UAB could participate in the Vocabulary of Research course operated by UAB's Clinical and translational Science Awards (CTSA) for medical fellows and researchers. Topics ranged from ethics, to study design, biostatistics and epidemiology. Staff trained at MDRF have increased MDRF's capacity in key research areas such as data collection procedures, data management, informatics, study operations and statistical analyses. For faculty and investigator level participants, the focus was on research methods, biostatistics, epidemiology, study design and management.

7. Video conferences:

A critical component of the success of the programme was the twice per month one hour video conferences. At the outset, one of these sessions was devoted to overall programme development and management and one was for joint scientific seminars. Technical challenges and the time difference made the seminar strategy less successful than it was expected so this activity was dropped and focused both sessions on programme operations.

8. Genomics/Genetics workshops:

This collaboration has helped in the implementation of a series of genomics training sessions, including lectures on genomics, genomic studies and workshops held in 2010-2012 and 2014. This was a separate set of training sessions, spanning a 3 or 4 day periods, attendees focused on genomic studies. Geneticist from various institutions and MDRF were invited as faculty for this workshop. The participants for this workshop included students interested to learn various hand on techniques in the field of genetics. All interested students were included in the workshop. These activities included lectures and hand-on demonstrations of basic molecular biology procedures and then advanced and recently developed methodologies of genetic analyses, including next generation methodologies.

Results

Figure 2 presents the countrywide distribution of seminar participants between the year 2003 and 2016. The International seminar played a critical role in building awareness and in building credibility for research in the field of NCD's not only in India but also in the South East Asia Region. The annual training seminars which started as national became international in scope with participants from Bhutan, Cambodia, Maldives, Nepal, Sri Lanka, Thailand, Vietnam and some from the US. Although involving participants from other countries, the major focus was on undergraduate students, post graduates and faculty

from India's medical colleges, primarily from community medicine departments. Applications were invited from India's 350 plus Medical Colleges and have had 1,471 representatives from most of the states in India, including the North eastern states, as shown in the figure.

Table 1 shows that a total of 1,471 delegates, typically undergraduate and post graduate medical students, epidemiologists and community health specialists in NCD research from 96 institutes and medical colleges from all over India and other countries, have participated in the National Seminar; 463 delegates in the Intensive Interactive Sessions; 883 in the MDRF in-house workshops, some several times; 244 in the training on the advanced techniques in genomics; and 37 in short-term training in the US, 18 of whom were women and three were from India's the north east region. Over 3,000 delegates from various medical colleges participated over the years, some attending more than once.

Table 2 presents the number of delegates who participated in clinical research and capacity building training workshops, classified by medical college site and year (2009-2016). Overall a total of 2,179 delegates participated in these training workshops. One workshop at KMC-Manipal in 2015 included 6 platform and 65 poster presentations.

Discussion

For training models focusing on NCD clinical research, there is a long history of degree seeking training, for both master's and doctoral degrees, plus numerous short-term training seminars and workshops. A long standing example of NCD-focused short-term training is the Ten Day International Teaching seminar on Cardiovascular Disease [6] with the 47th annual session in Fiji in 2015. These sessions, typically including a strong international faculty and 36 international scholars, were held in Mysore, India, in 2014. Two other important examples are the American Heart Association Ten-Day Seminar on the Epidemiology of Prevention of Cardiovascular Disease [7] initiated in 1975, typically with 32 scholars per year, and The American Thoracic Society Methods in Epidemiologic, Clinical and Operations Research Program launched in 1994 [8]. The latter is an extensive programme which includes training for clinical practice as well as for research methods in numerous countries, including India, and has now trained at some level over 1,000 trainees. Until very recently most public health training programmes in India, undertaken largely by the Preventive and Social Medicine or Community Medicine Departments of medical colleges, focused on the problems of communicable diseases, health, hygiene and under nutrition. There were few training opportunities focusing on prevention and control of NCDs, which led to this evolution of the ICOHRTA Program.

This programme evolved over time, in response to feedback received from faculty and delegates, the evaluation process, and to the changing needs in India. A total of fourteen national seminars was conducted between 2003 and 2016. Annual training seminars were the focal point for increasing awareness of the diabetes and NCD burden in India and nearby countries. The approach to addressing the NCD issue in India via training workshops in various institutions apart from MDRF has proven popular. The focus was on increasing

capacity in clinical, translational and implementation science across India, and beyond, and on addressing the research needs associated with this burden.

Notably, eight of the 37 short-term trainees have completed their PhDs, six others already had MDs or PhDs and several now have very responsible positions at their institutions, including one Head of Medicine. Of these short-term trainees, 8 have been granted 24 projects by various international and national funding agencies. Importantly, some 25 of the delegates for the MDRF in-house workshops have now completed their PhDs and several more are in progress. MDRF researchers have published over 400 articles in peer reviewed journals since 2002.

Some who initially attended the Intensive Interactive Sessions subsequently served as faculty for the National Seminar. Capacity building was enhanced by providing training for nine District Nodal Officers from six states for the National Prevention & Control Programme for Diabetes/Cardiovascular Disease/Stroke (NPDCS).

The collaborative training programmes have played a critical role in building awareness and in building credibility for research and for research careers in the field of NCDs among scientists not only at MDRF but across India especially its numerous medical colleges. Within a span of 14 years, over 5,250 physicians, community medicine and public health specialists have been trained through a network of 122 physicians and scientist, both international and national, working in the field of NCDs. With this collaboration the research capacity of MDRF has been increased significantly due to the training opportunities that the grant has provided and are bringing this new knowledge to bear on the ongoing research. Centre leaders and staff have benefited by receiving practical guidance, research and statistical skills, and gained new knowledge, increased confidence, and improved approach toward research in the field of NCDs. Many trainees were in the very early stages of their careers so that the activity helped them develop foundation for a solid career focusing on the NCDs epidemic in India. The ICOHRTA training programme was the only NCD training activity conducted in India in 2001 and serves as a model for capacity building for prevention and control of NCDs in India [Figure 3].

In all the programmes, the feedback obtained from both faculty and participants were scrutinized carefully and necessary actions were taken in the subsequent year to improve the quality of the programme. The feedback provided was subjectively assessed. The limitation of this programme is that no quantitative assessment was done. Hence the enhancement of the participants' skills/ knowledge could not be assessed.

The success of the programme served as a model for others to conduct similar programmes in other parts of the country (Kerala, Chandigarh, New Delhi). Despite these accomplishments, however, much remains to be done as India addresses a veritable tsunami of NCDs and related conditions. Thus, a collaborative effort by government authorities and agencies, public health training institutions, and key players in the field of NCD prevention and control would play a big role in reducing the threat of NCDs in India through public health training.

CONCLUSIONS

The clinical research training and capacity building that began under the US NIH Fogarty International Center's ICOHRTA Program and then continued under the LifeSpan Program serves as a model for meeting NCD and other training needs. The programmes conducted continuously over a period of 15 years, has helped to increase research capacity and research methodology skills of trainees and collaborating institutions somewhat broadly in India. While this is an important accomplishment, much more work is needed to address the magnitude of the NCD burden which is rapidly increasing in India and other developing countries.

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Figure 1:
ICOHRTA programme for NCD capacity building & its collaborators

Figure 2:
Countrywide distribution of seminar participants (2003 - 2016)

Figure 3:
The MDRF-UAB-FIU model for capacity building for prevention and control of non-communicable diseases in India (from 2003)

Table 1.

Number of delegates attending training and capacity building programmes, classified by type of training activity and year for sessions held at MDRF and in the US, 2002-2016

Activity	Before 06	Year											Total
		06	07	08	09	10	11	12	13	14	15	16	
US Training	12	-	4	4	4	4	2	3	-	3	1	-	37
National Seminar	291	113	103	101	106	108	112	100	116	103	102	116	1,471
In-house Workshops	116	70	61	68	65	70	68	70	75	75	70	75	883
Intensive Seminar	20	19	28	33	30	32	45	53	61	53	47	42	463
Genomics Workshop	-	-	-	-	50	54	55	15	-	41	29	0	244
TOTAL	439	202	196	206	255	268	282	241	252	275	249	233	3,098

Table 2.

Number of delegates participated in clinical research and capacity building training workshops, classified by medical college site and year, 2009-2016

<i>Medical Colleges</i>	Year								Total
	09	10	11	12	13	14	15	16	
KMC-Anand, Gujarat	45	-	-	-	-	-	-	-	45
KMC-Manipal, Karnataka	-	-	145	151	200	200	250	-	946
GMC, Assam	-	-	195	205	195	-	-	-	595
FAAMC, Assam	-	-	-	-	151	-	-	-	151
PIMS, Puducherry, Tamil Nadu	-	-	-	-	-	-	143	102	245
NEIGRIHMS, Shillong	-	-	-	-	-	-	-	197	197
Total	45	-	340	356	546	200	393	299	2,179