



Review Article

Clinical Epidemiology in Developing Countries: Current Situation and Suggestions for the Indian Context

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Abstract

Background

In India Epidemiological services are well developed and epidemiology teaching is very much part of the curriculum from undergraduate level. Clinical Epidemiology (CE) is not popular and the initiatives to sensitize physicians towards clinical epidemiology were started by International Clinical Epidemiology Network (INCLEN).

Objectives

This review article is aimed to describe the evolution of CE in India and critically look in to the concept and scope of CE and Evidence Based Medicine (EBM) in the Indian setting.

Methods

This paper is a review of the status of clinical epidemiology popularisation and the scope for further progress in this direction.

Results

The development of clinical epidemiology has taken a new pace after the introduction of Evidence Based Medicine (EBM). Both CE as well as EBM is propagated by INCLEN trained faculty and the paper also looks in to the linkages between public health epidemiology and clinical epidemiology in the context of involvement of clinical epidemiologists in public health programs.

Conclusions

After discussing the directions for future, the paper proposes the inception of clinical epidemiology unit at each medical college and also the objectives and structure of such a unit. The article concludes emphasizing the need of public health orientation of clinical epidemiology, the importance of promotion of epidemiology in developing countries through capacity building and allocation of dedicated funds and replication and scale up of CEU model to other medical colleges.

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Introduction

Epidemiology in medicine or Clinical Epidemiology (CE)

CE has now gained a well established footing in academic institutions especially in developed countries. In the context of the established network of 'epidemiology teaching learning centres', CE is slowly becoming popular in the schools of medicine in India also [1,2]. Originally epidemiology was evolved as a fundamental science of public health. When the importance of application of principles of epidemiology in the bedside setting for improving clinical outcomes was recognized, the branch of clinical epidemiology was slowly accepted. During the course of evolution of organized health care, the dichotomy of public health and clinical medicine was inevitable and discussions on this dichotomy still continue. This schism as it was coined by KerrL White can be considered as one of the causes of low popularity of CE among clinicians [3]. Clinical practitioners are always concerned with the immediate benefits for their patients and may not use epidemiological principles in their daily practice unless it is convincingly useful for immediate patient benefits. With the evolution of the branch of clinical epidemiology, with tools like diagnostic test evaluation, prognostic prediction, and clinical trials and meta-analysis, CE is becoming more and more popular among clinicians. This may be the main reason for popularity of epidemiology among clinicians rather than merely an attitude of altruism towards scientific practice of medicine. The altruistic concept of practice of medicine as it was discussed needs a deeper understanding of public health [4]. The criticisms about use of epidemiology by clinicians were discussed in detail by Paul K Whelton [5].

Public health and clinical epidemiology

After discussing about the popularity of epidemiology in clinical medicine let us discuss on the applications of epidemiology in public health. In the public health context, application of epidemiological principles is more for prevention than for treatment. Integrating prevention to routine functioning of health services was mostly through implementation of public health programs as governmental responsibility [6]. The public health programs in India are supported by epidemiological database and monitoring and evaluation also are periodically done based on epidemiological principles. During the implementation of at least some of the public health programs, private sector which has the vast majority of the practicing clinicians in the country was not taken into full confidence. Of late this strategy in India was changed and the tuberculosis control program is a typical example of effective public-private partnership [7]. The private-public dichotomy is perhaps more crucial than the so called 'public health-clinical schism' in practice and popularisation of clinical epidemiology in India.

INCLEN and CE in India

Popularisation of CE was formally started in the developing countries with the origin of International Clinical Epidemiology

Network (INCLIN) in 1980s [8]. This new network was evolved around academic institutions in order to enlighten clinicians on the need to understand and look critically at available interventions and medical literature, to popularise rational approach to treatment which is effective, efficient and acceptable to the patients. The overall purpose was to develop patient oriented researchers and clinician-investigators who can undertake quality research. Though trained to excel as clinicians and propagate clinical epidemiology, many of the INCLIN trained fellows later on took interest in public health research also which led to better partnerships between academic community medicine departments, program managers and other researchers. The schism between public health epidemiology and clinical epidemiology was thus converged in a more harmonious manner in India. Clinical orientation of medical research is emphasized by researchers and this is relevant to India also [9]. A sizable part of clinical research is supported by the drug industry which has limitations in getting the clinicians in public sector to collaborate with them. The Governmental machinery was also in demand of services from the new group of academic experts specialised in clinical epidemiology and they positively responded to this demand which was only natural. In addition to their commitment to the original mission of INCLIN to popularise clinical epidemiology, the INCLIN fellows in the country continued to involve in public health activities also. The three branches of analytic domains namely clinical epidemiology, clinical economics and health social sciences continued to flourish, supporting all these research activities in the country. An attempt to apply epidemiologic approach to bedside medicine has gained an accelerated momentum when EBM movement started and CE became the major support science for EBM practice in India also. This new facelift in popularisation of clinical epidemiology by equipping medical schools with departments of CE and EBM has many challenges which are applicable in the Indian context also [10,11].

In India, epidemiology is very much a part of curriculum in undergraduate courses and presently the department of community medicine is primarily the agency to teach epidemiology. The very purpose of establishment of Clinical Epidemiology Units (CEUs) in medical colleges initiated by INCLIN was to sensitize the clinical faculty towards these broader branches of health sciences which are new and conceptually cross cutting across different specialities of medicine [12]. This was also to introduce the concepts of outcome based research, critical appraisal, cost effectiveness and other qualitative and quantitative research methodologies. Presently we have nearly 20 such CEUs working in India under the leadership of India-CLIN, which is a country level partner of the INCLIN. The qualified clinical epidemiologists and those fellows trained in clinical health economics and social sciences continue to serve as resource persons in their vicinity. India-CLIN started in 1990 with initial six CEUs continue to propagate CE and EBM in the country through teaching learning activities like regularly conducted journal clubs and seminars.

How far is the idea of clinical epidemiology sold in the Indian context?

There is no doubt that CE has now become a prudent and well distinctive medical specialty as any other academic discipline. The recent editions of text books and journals and the separate establishments of departments and courses including PhD programs speak as evidence for this [13,14,15]. In the Indian context, the origin of CEUs and academic deliberations in the medical schools with

the involvement of INCLIN trained faculty is yet another evidence for this. Only very little of the work of this facility so far appeared in the national limelight as policy implications. The India-SAFE project (Survey of Abuse in Family Environment in India) which paved way to the domestic violence act in India, the IBIS project (Invasive Bacterial Infection Study) which led to the revolutionary changes in pneumonia management are only few examples. What is more important is the new thrust on quality of medical research which is visible in many of the medical schools which own these CEUs. Engendering the culture of sound methodological research through epidemiological approach has been taken as a mission by this faculty. Of course being the members of institutional ethical committees of the respective medical schools where they work, they could also direct many of the research projects towards more prudent human subject protection. By their activities they could also facilitate more intramural as well as extramural funding for research. As research is something which cannot show immediate visible results the long lasting output of all this will take its own time.

The uncertainty continues

Clinical decision making is the cognitive element of scientific medical practice. For diagnostic decision making or choice of therapy at the bedside setting, the mind-set of the physician should change towards rationality and maximization of the patient benefit in a social perspective. This is a matter of professionalism and personal attributes of the practicing physician matters more than mere scientific knowledge. The availability of best research evidence is from journals or text books and to a certain extent, from standard practice guidelines. For assimilation of this particular knowledge base which is basically research-publication derived than text book oriented, critical appraisal skills are needed. Critical appraisal skills are simply based on principles of epidemiology. Those who have not understood epidemiology may find it difficult to involve in the process of clinical research. Clinical research is important for generation of evidence for changing clinical practice towards better patient outcomes. Epidemiology helps to decrease the element of uncertainty in diagnostic and therapeutic decision making process. The readers are requested to look previous articles which discuss the importance of clinical epidemiology and also the evolution of clinical epidemiology services in India which is helpful to understand the present article [16].

The role of EBM and other new concepts

There are many questions that any novice can ask. Is EBM same as CE? Is EBM a parallel concept and threat to CE? Though these are overlapping concepts, EBM and CE are not exactly identical disciplines. In fact both are complimentary [17]. CE and EBM are distinct not in terms of semantics only, but are separate domains with distinctive theoretical underpinnings, practical applications and different set of stakeholders for ownership. (An identical phenomenon of jargons is operational research, translational research and implementation research.) EBM is the point of care application of epidemiology and epidemiological approach is needed for posing the right question, evidence generation, evidence appraisal and using the evidence for appropriate decision making as well as incorporating feedback about the practice of EBM. Other overlapping academic disciplines like clinical governance and clinical excellence also have scope in the Indian context, especially with the new thrust on CE services and established CEUs. These are concepts developed towards more rational use of resources as well as well-defined standards of

care. Clinical excellence concentrates on identical methodologies and epidemiology helps for defining quality, outcomes, benchmarks and other standards for accreditation as well as auditing.

Thoughts for the future

What is the contribution of epidemiology for effective and efficient functioning of health systems in the Indian context? How we can increase it? Answers to this should come through further academic discussions. Perhaps the inception of CEUs in the country is only a good start by the great visionaries under the label of INCLEN. This mission is now facing newer challenges. Private-public divide is to be studied more seriously and clinical 'epidemiology-propagation' should be extended to the private medical establishments also. Involvement of clinical epidemiologists in activities related to public health programs need to be appreciated and more opportunities to be created. This should be seen as a means to bring down the gap between public health and clinical epidemiology (The original schism described by Kerr L White). Clinical practice is now facing other challenges like practice of defensive medicine, gate keeping by managed care, and increasing commercialization. The 'medical knowledge explosion' of present century warranting continued updating efforts by the practising physicians is another added strain. In this changed setting of clinical practice it is only natural that there will be emphasis on a newly defined quality and accountability-elements for clinical practice. This quality element of health care industry should have a strong foundation of professionalism and all clinical ombudsman activities should be evidence based. Here is the precise role of epidemiology and all evidence for rational practice should come from properly conducted epidemiological research, appraised by appropriate epidemiological methods and knowledge translational process should be evaluated by scientific methods. Clinical epidemiology services also should be considered as a part of all public health activities [18]. Clinical epidemiological approach should be made a basic analytical tool to be used by all clinicians at the bedside. Each practitioner should be asking the relevant clinical question about the patient and all practice to be transformed in to EBM activity. As there is considerable resource limitation in developed country setting, the efficiency and equity considerations are more important concerns in the Indian context. There should be reorganization of the medical curriculum including more topics on clinical epidemiology, clinical economics (can be considered as a branch of health economics), qualitative research and bioethics. Capacity generating activities in the medical schools towards accomplishing all these thoughts to reality is the foremost priority in the Indian context. The establishment of a Clinical Epidemiology Unit (CEU) is a basic step and a humble beginning towards this long cherished and noble mission.

Proposed structure of CEU

As initiated by Inda CLEN, (Indian Clinical Epidemiology Network) the Clinical Epidemiology Unit will consist of six clinicians, one social scientist, one biostatistician and one health economist. The importance of health economics in clinical medicine is now well known [19,20]. These nine medical teachers will be selected from among the middle level faculty members. A senior level faculty member was trained to become the director of the centre. The principal of the institution acts as sponsor and the head of the Unit.

Objectives of CEUs

1. To train sufficient number of middle level faculty members in the medical colleges of the state, and to make them skilled enough to impart CE training to graduate and postgraduate students of these institutions.
2. To conduct affiliated courses in clinical epidemiology like MPhil like the courses in CE centres in McMaster, UPEN (University of Pennsylvania) etc. The curriculum includes clinical epidemiology, biostatistics, health economics, health social sciences information technology and management. The awardees of this course can function as consultants for research projects as well as teachers in epidemiology and occupy the posts of epidemiologists and assist the Government in policy matters related to health problems and priorities.
3. To achieve capacity building through necessary modification of human resource infrastructure and influencing for modification of curriculum for graduate and postgraduate course in medicine.
4. To undertake good quality research projects for primary data generation in selected areas for addressing the gaps in data for public health planning.
5. To undertake collaborative clinical trials. The network capacity and expertise helps for this. At present the pharmaceutical industry is supporting clinical research and units like research clinical centre in some western hospitals can be adapted as role models for functioning of CEUs.

Conclusion

For scientific practice of medicine in developing countries, research methodology need to be widely promoted, epidemiology need to be more popularised and more funds need to be channelized. Local research capacity building is fundamental to this and generation of evidence also need to be more context specific than imported from other areas.

Public health orientation of clinical epidemiologists is important because as CE is application of principles of epidemiology in bedside, the domain of CE may continue as the story of the so called 'abnormal'. Physicians should have a say in the maintenance of health, because they are the primary advocates and advisers of people in all matters of health. The linkage to public health activities is only a means for that. The new group of clinicians with more public health orientation will certainly take lead in development of clinical epidemiology. The CEU model is perhaps the easily replicable one for propagation of CE and EBM and facilitating public health orientation of clinicians especially for the developing countries.

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