# COFFEE BOOK on Policy Research





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# FOREWORD

Policy Research is in infancy in India and requires thrust by funding agencies. Evidence based formulation of policy in science requires rigorous PhD programs which pursue compelling research questions relevant to management of research and its development. In view of



this we have continued to write policy briefs such that it evokes policy research activity in India. By identifying the barriers in conducting smooth research, it is possible to form new guidelines that promotes research. The articles compiled here fulfill such gap in Indian research.

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# Traditional Medicine as a part of Indian healthcare system: Challenges and Recommendations

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#### **KEY WORDS**

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ABSTRACT

Traditional Medicine Challenge Recommendation Health care System **Background:** Traditional Medicine (TM) is a system of medicine which is a combination of medical theories of various cultures, which can help in health maintenance, disease prevention and diagnostics. But this system of medicine has not been globally recognized and accepted, due to numerous reasons including, lack of research, technology, funding, etc.

**Summary:** The present review focuses on discussing the gaps and limitations at both academic and administrative levels in the acceptance of TM as a part of the Indian Healthcare system. Certain *in vivo* and *in vitro* studies have been discussed in the present review, showing the beneficial effects of TM on various health conditions. Based on the discussed studies and limitations, the authors have further proposed certain recommendations, including documentation, national policies, and academics that can be helpful in the implementation of TM as a part of the Indian healthcare system.

**Key message:** Through the present study, the authors have proposed that TM is an important part of the healthcare system, and this can be combined with conventional medicine to reduce the burden on the healthcare system in India as well as globally.

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### Background

Traditional medicine (TM), as defined by the World Health Organization (WHO), is the combination of knowledge, skills, and practices which are based on the theories, beliefs, and experiences belonging to various cultures. These can be used in health maintenance as well as in the diagnostics, prevention, and treatment of physical and mental ailments (1). TM is the combination of health practices which comprises of plant, animal, and mineral extract-based medicine along with spiritual and manual techniques, and certain exercises with the combined aim of treatment, diagnosis, and prevention of illness along with the maintenance of well-being (2). TM has always been an important system of medicine that is essential for maintaining global world health needs. In the Indian scenario specifically, six systems of medicine are recognized in this field: Avurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy. Each system of TM is important in its context (3).

Besides each of these systems having its advantages, these are not globally accepted in the current scenario and face challenges in being accepted as an important system of Medicine. Though the above-mentioned systems of medicine have originated in India, the acceptance and recognition of these are not ubiquitous (4). Many factors have led to the current scenario with allopathic medicine taking the front end of the medicine system and other TM systems are not being commonly recognized as a system of medicine for disease prevention and cure.

Though a huge volume of studies is available in support of the TM system (5), many factors limit the potential of the TM system to make it globally acceptable. Through the current study, the authors wanted to highlight the challenges in the implementation of TM in the current system of medicine, specifically in the Indian context. Further, the authors have also provided certain recommendations for the implementation of TM along with the current healthcare system.

TM system faces many challenges in the implementation of TM in daily lifestyle as a part of disease preventive and curative strategy. Following are some of the challenges which are faced by policy members in the following context (6).

#### **Academic limitations**

#### Lack of research and development in the field

The evidence-based studies are lacking in the field of traditional medicine. Small sample numbers, inconsistent or varied outcomes, and poor research methods are some of the key factors that render studies defective and insufficient. Other issues include weak controls, inconsistent descriptions of the treatment or product, low statistical power (perhaps due to small sample sizes), and a lack of comparisons with other therapies, a placebo, or both (7). Folk traditions and wisdom of traditional medicine are handed over from generation to generation in India and are termed as 'people's health culture' with the scarcity of documentation and patents in the field of traditional medicine. As per the announcement by the Ministry of Commerce and Industry, any readymade traditional ayurvedic formula cannot be patented, however, substantial improvement and modification in this area can be patented, hence the number of patents in the field of TM is required to generate more data and evidence-based documentation (8) and hence patent in the field of TM can be used as a tool of evidence and market awareness. Obtaining patents with modified and improved TM components also enhances entrepreneurship potential.

Lack of technology to preserve the research data: While there is an increasing trend with the use of TM worldwide, the research in this field is inadequate with serious difficulties in data acquisition and preservation. The research data generated is not safeguarded and preserved in a way that it can be retrieved and reproduced. The data once acquired has to be stored in a way so that it can be retrieved from the repository.

Lack of SOPs (Standard Operating Procedure): Despite the rising research and acceptance of the field of TM, certain studies are reporting adverse health effects of TM, this may be due to the variable quality, efficacy, and contents of herbal products as a class of medicinal products. In this regard, the development of SOPs for carrying out research studies based on TM could help generate evidence-based research data, also the data generated could be patented based on standard operating protocols used (9).

Lack of funding: There is a lack of higher education support system in traditional medicines such as Ph.D. and Post Docs. Traditional medicine is primarily practiced by folk people or indigenous communities and from here only limitations appear and hence, the general population access gets restricted (10). When government will promote Ph.D. research fellowships and Post Doc fellowships, only then a large number of communities will become part of the standardization and quality assurance in traditional medicine (11). Medical institutes should bring courses for learning as well as training of TM so that from here only the development of collaboration of modern medical system with traditional medicine can start (12).

*Lack of high-impact TM journals*: For the wide acceptance of research, publication in high-impact journals is paramount, but a limited number of high-impact journals consider publishing research data on TM due to limitations in the research data, and also due to the lack of approval to TM research (13).

#### Administrative limitations

*Lack of administrative bodies*: There is a lack of administrative policies specially made for traditional medicines. In Medical institutions, there should be a separate ethical committee and Dean for approval of doing Traditional medicine research (9). These committees should contain medical experts as well as people who are experts in traditional medicine. This

collaborative method might yield good results as well as be helpful in the standardization of outcomes of every traditional medicine study (14).

Policies and regulations, development and enforcement: In TM, there is a wide range of products, techniques, and practitioners. Some of these techniques are aimed to provide health benefits, while others have their risks or are solely motivated by business interests. Government should choose where to concentrate its efforts given its limited resources to give consumers the greatest and safest type of healthcare while meeting the requirement to protect consumer choice and it must be supervised within their jurisdiction. In TM systems that are referred to as codified medical systems, policymaking, and standardization are arguably the most challenging issues (15). For instance, some courses might place more emphasis on the physical parts of the healing system than others, which might place more emphasis on the mental and spiritual aspects. For this to be done correctly, it would be necessary to have policies and particular nodal agencies to control and offer guidance (16). As per the WHO report in 2004, to implement TM in any country's healthcare system, formulation and implementation of national policies and laws as per the country's situation are needed (17).

*Lack of awareness among medical practitioners about TM*: For the integration of TM into the conventional healthcare system, medical practitioners should be made aware of the system of TM, which could generate more evidence.

# *Lack of documentation of TM leading to lack of transfer of knowledge of TM to future generations*

Lack of documentation is one of the major hurdles in the acceptance of TM, which could be due to the limited documentation of traditional medicine-based medicine through, research papers, clinical trials, and well-documented libraries, which could preserve the information. The preserved information could have then been passed on to future generations. Due to lack of proper documentation, knowledge transfer has been majorly impacted leading to less acceptance of the TM system of medicine in the masses. To overcome the issue, Government has now initiated the Traditional Knowledge Digital Library (TKDL), which is a digital repository of knowledge of TM. This repository is currently under the AYUSH ministry.

# Lack of awareness and acceptability of the consumers concerning TM

In contrast to Western biomedicine, these medical traditions have a distinctive understanding of physiology, aetiology, pharmacology, and medicines (18). These medical systems have recently become professionalized, maybe as a result of this systematic approach. Traditional medicine refers to those traditional knowledge systems that are more frequently passed down orally, were developed by communities over many years, and utilize readily available and accessible elements of the local ecosystem (15). Government should focus on advertisements, researchers, applicability, and implementation methods for the optimal use of TM.

*Industrial development*: Due to a lack of patents and entrepreneurship in the field of TM, this stream has not been established well in the field of industries, and hence people self-medicate as per the oral transfer of the knowledge of the field which may generate negative health effects. There is a need of enough evidence to generate optimum industrialization in this field through patents, documentation of SOPs, and storage of data to stimulate standardized drug industrialization in the field of TM.

*Quality*: Implementation and functioning of Inter-University and inter-medical institute nodal centres are required to generate enthusiasm and data out of collaborative research between various Institutions through student impart training and Inter-University projects.

AYUSH and health secretariat collaboration- The anticipated unification of the nation's Traditional Health and Modern Medical systems can be achieved through the implementation of a clearly defined procedure (18). AYUSH and the modern health secretariat should collaborate for access to generalized facilities, and find task forces and administrative portfolios which are already available. To further the process of coordinated action and achieve complete integration of both ministries at all functional and conceptual levels, a monthly joint review mechanism might be created (19).

Lack of Integration between Western Medicine and Traditional Medicine- Integrating traditional medicine into a modern healthcare system can benefit industrialized nations as well (20). There should be a Centre for Training and Learning established inside every hospital. To improve the staff's knowledge, skills, and general capacity, the Institutions should hold frequent academic meetings of various kinds related to traditional medicine so that their knowledge can embark with current knowledge in the field (21). A significant barrier to the incorporation of TM into mainstream medical practices is the absence of pharmacological and clinical data on the bulk TM items. Pharmacological and, in particular, comparative effectiveness, clinical research, must be done (22).

#### Integration of TM into National and Primary Healthcare

A Joint health secretary must be appointed to support and direct the execution of national policies on indigenous medical practices and to promote the resurgence of those practices (23). The development of India's national health strategy should include traditional medicine experts.

# Comparative *in vitro* and *in vivo* studies on scientific validation of TM

A double-blind, placebo-controlled randomized study, tested the efficacy of pennogenyl extracted from French maritime pine bark extract which has been known for its clinical efficacy in lowering blood glucose levels recruited N = 147 prediabetic participants above the age of 18 with FPG between 5.5–6.9 mmol/L and BMI >25 kg/m<sup>2</sup> and compared this with standard placebo who were given an extract containing NaCl with other excipients except for maritime pine bark extract. The participants were tested for the efficacy of pine bark extract by measurement of FPG and other parameters but in this study, the authors were not able to find any improvement after 12 weeks of intervention. However, the study had its limitation concerning the duration of intervention, nonstringent recruitment criteria and the participants had a wide initial FPG range (24). As per a study published in the JAMA network in 1998, which investigated by a survey of 1035 individuals for examination of choosing traditional alternative medicine over conventional treatment, it was reported that the major contributors to choosing traditional medicine were higher education and poorer health status, also it was reported that one of the major reason for choosing traditional medicine over conventional was being dissatisfied with conventional medicine also alternative medicine was as per their values, beliefs and philosophical orientation towards life (25). A survey-based study on the usage of traditional medicine over conventional medicine among the general population in a city in Malaysia reported that 31.7% of the total recruited population having traditional medicine over conventional for self-management of cardiovascular health conditions as they were not prescribed to take the traditional medicine, which highlights the need of research-based studies on traditional medicine to avoid self-mismanagement of cardiovascular conditions (26). A study randomized controlled study in 2019, identified the effectiveness of adjunct yoga therapy over conventional therapy in diabetic lung patients where N = 72participants were randomized in adjunct yoga and control group. The adjunct yoga group was given yoga training thrice a week for 4 months and assessed for the efficacy of adjunct yoga in the improvement of pulmonary function in diabetic lung patients. It was observed that the yoga group showed a significant change in weight and BMI after 4 months, also the yoga group showed a significant improvement in pulmonary functions i.e., FEC1 (Forced expiratory Volume), FVC (Forced Vital Capacity), and in case of conventional therapy, these parameters worsened with time (27). Another yoga-based study identified the efficacy of yoga-based traditional medicine in a primary care setting, where participants with high blood pressure (Systolic Blood Pressure of  $\geq$ 140 mmHg and <160 mmHg or Diastolic Blood Pressure of ≥85 mmHg and <100 mmHg) or those who were taking medication for high blood pressure were recruited and randomized into control and yoga groups, the control group was following the conventional lifestyle or medication (if any), the yoga group was given initial 5 days physical yoga intervention in the primary care centre followed by at least 30 minutes of yoga practice to be done at home for 90 days, after yoga based traditional medical intervention, a significantly reduced systolic and diastolic blood pressure was observed. Based on these results it can be hypothesized that the addition of yoga as a standard treatment approach could be preventive for the development of major NCDs like hypertension (28). A study assessed the

response of neem leaf extract inoculation on animals with Ehrlich Carcinoma (EC) which was inoculated in animals by regular in vivo intraperitoneal passage under sterile conditions and Murine B16 melanoma cell line was also maintained under standard culture conditions, when the C57 animals and B16 cell were inoculated with (1 unit/mice/week for 4 weeks) Neem Leaf extracts, significantly reduced tumour growth was observed in both Ehrlich Carcinoma and B16 melanoma cell line, no in vitro cytotoxic effects of neem leaf extract was observed towards both EC and B16 Mel tumour cells. Another study identified the anti-tumour effect and immune-modulating effects of an extract of the plant Calendula Officinalis (Asteraceae) on cell lines derived from leukaemia, melanomas, fibrosarcomas and cancers of the breast, prostate, cervix, lungs and pancreas by BrdU incorporation and analysis of total cell count. Also, nude mice which were subcutaneously injected with human Ando-2 melanoma cells were tested for anti-cancerous effects of plant extract Calendula Officinalis (Asteraceae). The plant extract showed a potent tumour inhibition in all the tested cell lines, further when the nude mice were provided with the extract obtained from the plant, it also showed inhibition of in vivo tumour growth (29). Adding on a few more studies related to Ayurveda and COVID-19, one study on an innovative herbs-mineral formulation called ZingiVir-H was created as an add-on therapy for adult patients with mild to moderate COVID-19. ZingiVir-H was proven to be efficient and secure in treating COVID-19 infections and postponing the disease's progression from mild to moderate and moderate to severe in a randomized controlled single-blinded multicentre clinical trial (30). In one another study, It has been demonstrated that the Ayurvedic formulation AYUSH 64 works well in easing the intensity of COVID-19 symptoms. AYUSH 64 was proven to be both safe and beneficial in lowering the length of hospital stays and the risk of hospitalization in a thorough multi-centre clinical investigation for the care of mild to moderate COVID-19 patients (31). In mild to moderate COVID-19, a pilot clinical evaluation of an add-on Ayurvedic formulation combining Tinospora cordifolia and Piper longum revealed that adding this formulation to standard therapy shortened hospital stays and recovery times. However, additional study is required to validate these results (32).

# Recommendation for optimal TM use in Indian health system

As traditional medicine has been a topic of discussion for many now. It is a challenge to preserve, maintain and maximise the usage of the ancient science of healing.

There are 15 agroclimatic zones in India, with 47,000 plant species and 15,000 medicinal plants. Around 7,000 of the 150,000 medicinal plants are used in Ayurveda, 700 in the Unani system, 600 in the Siddha medicine system, and approximately 30 are used in the modern medicine system. This makes India one of the mega bio-diverse countries in the World (33). The recommendations for enhancing the usage of TM in the Indian health system need the correction of flaws

discussed in the challenges. The national health system in India is being integrated with traditional medicine (TM) using a two-pronged strategy. The main strategy is to advocate for the use of TM as an additional or alternative therapy, and the second strategy is to incorporate TM into the established healthcare system. The National AYUSH Mission, which began operations in 2014, is carrying out the main strategy. Through several activities, such as the creation of AYUSH dispensaries and polyclinics, the education of AYUSH practitioners, and the manufacture of AYUSH medications, the mission seeks to promote the use of TM. The National Accreditation Board for Hospitals and Healthcare Providers (NABH) is carrying out the secondary plan. Hospitals and healthcare organizations are accredited by NABH, an organization supported by the government. A new set of requirements for hospitals integrating TM was introduced by NABH in 2017. A few key points are covered by these standards such as the accessibility of TM professionals, accessibility of TM drugs, the instruction of medical professionals in TM, the inclusion of TM in a patient's entire care plan etc. It takes a lot of work to incorporate TM into the Indian healthcare system. The government's twopronged strategy, though, is a promising beginning. The government is working to guarantee that all Indians have access to quality healthcare by encouraging the use of TM as a complementary or alternative medicine and by incorporating TM within the established medical system.

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#### Advanced technology and documentation

- 1. Indian traditional medicine being the ancient science of healing need maintenance, preservation and curation for reducing the economic burden, which can be done through the advanced approach of technology like artificial intelligence, machine learning and the development of a database for information (34).
- 2. There is a lack of IP Protection or standard documentation for traditional medicine knowledge. The documentation is complicated and a potential challenge, which needs continuous effort for resolving the issue. Unresolved issues can lead to the loss of IP protection, lack of resources, legal challenges for ownership and failure in the utilization of traditional medicine knowledge (35).

### Collaborations

- 1. The Ministry of Health, AYUSH, Science and Technology should be encouraged to collaborate with different institutes for more clinical, research, technical and Scientific growth and to Produce more evident based ancient science of healing.
- 2. Therapies under traditional medicine are valuable and effectively used worldwide, especially in the United States and other Latin nations. Considering that a collaboration workshop was conducted in March 2016 between the Ministry of AYUSH, Govt of India and different Institute of US like NCI (National cancer

institute), NIH (National Institutes of Health), and Office of Global Affairs, US Department of Health and Human Services (36). The result of the workshop decided standardization of TM products and make them more reliable and more scientific with the production of research and clinical trials.

- 3. Collaboration with other countries and different government agencies will also generate the resource for funding. External collaboration can enhance the ideas, approach and motivation for new concepts (35).
- 4. The time-to-time validation and assessment of information on traditional knowledge applicable to the Indian Health System.
- 5. There is unrecognised work by Ground innovators, who have been working in the field for years, should be encouraged and supported for registration, filing the patents, Claiming of IPR (Intellectual property rights) and other legal knowledge associated with it by the government.

#### National policies for traditional medicine

- One of the reasons that lead to decreased demand for TM could be extensive national policies for ancient medicine. The role can be defined effectively and efficiently, by developing national policies needed in the health sector. Lack of policies and lack of government oversight, reduce the usage for people around the nation. Policies can build a necessary regulatory and legal mechanism, to promote and maintain good practices, that make TM equitable and accessible with more authenticity, safety and efficacy of therapies used (37).
- 2. Many developing countries all over the world have emerging TM policies. The Indian health system should make policies to assure the preservation and maintenance of Traditional medicine through different advanced techniques like artificial intelligence, Machine learning and Developing software to secure our ancient science of healing.
- 3. According to a survey done by WHO, only five nations had policies for TM in early 1990, by 2003 the number have reached 45 nations and 51 nations were still making policies for TM (38).

# Integration of TM into national and primary healthcare

A joint health secretary must be made to support and direct the execution of national policies on indigenous medical practices and to promote the resurgence of those practices. The development of India's national health strategy should include traditional medicine experts.

#### Conclusion

TM is an important system of medicine which could be an addition to conventional medicine if integrated and can also help reduce the burden on conventional medicine in the current system. TM is not a new era or new concept towards health. However, with the acceptance of TM in the Indian healthcare system, various challenges are currently in the acceptability of the TM medicine system which the authors have highlighted in the present review. The authors have tried to provide certain recommendations towards the acceptance of TM in the current Indian Healthcare system. For the implementation of the suggested recommendations, both state and national policies have to be implemented for the integration of TM with the conventional medical system in Indian Healthcare.

#### Authors' contribution

KPS: Writing and editing; MG: Writing and editing; SKC: Writing; AA: Conceptualization and editing.

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#### References

- Srinivasan P. National health policy for traditional medicine in India. In World health forum 1995;16(2):190–193, 1995.
- Fokunang CN, Ndikum V, Tabi OY, Jiofack RB, Ngameni B, Guedje NM, Tembe-Fokunang EA, Tomkins P, Barkwan S, Kechia F, Asongalem E. Traditional medicine: past, present and future research and development prospects and integration in the National Health System of Cameroon. African journal of traditional, complementary and alternative medicines. 2011;8(3).
- Howland O. Fakes and chemicals: indigenous medicine in contemporary Kenya and implications for health equity. International Journal for Equity in Health. 2020 Dec;19:1–2.
- American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2021. Diabetes Care. 2021;44:S15-33.
- 5. Sacks D, Baxter B, Campbell BC, Carpenter JS, Cognard C, Dippel D, Eesa M, Fischer U, Hausegger K, Hirsch JA, Shazam Hussain M. From the American Association of Neurological Surgeons (AANS), American Society of Neuroradiology (ASNR). Cardiovascular and Interventional Radiology Society of Europe (CIRSE). Multisociety consensus quality improvement revised consensus statement for endovascular therapy of acute ischemic stroke. Int J Stroke. 2018;13(6):612–32.
- Srinivasan P. National health policy for traditional medicine in India. In World health forum 1995;16 (2):190–193, 1995.
- Nahin RL, Straus SE. Research into complementary and alternative medicine: problems and potential. Bmj. 2001 Jan 20;322(7279): 161–4.
- Ministry of Commerce and Industry, Patents to traditional ayurvedic medicine, Press Information Bureau, 2013.
- Ali A, Sumbul S, Ahmad MM, Ahmad S, Kabir H, Abdin MZ. Development of standard operating procedure and standardization of Habb-e-Banafsha Qawi-A Unani polyherbal formulation. Journal of Pharmacy & Bioallied Sciences. 2015 Oct;7(4):250.
- 10. Ijaz N, Boon H. Statutory regulation of traditional medicine practitioners and practices: the need for distinct policy making guidelines.

The Journal of Alternative and Complementary Medicine. 2018 Apr 1;24(4):307–13.

 Kumari R, Kotecha M. A review on the Standardization of herbal medicines. International Journal of Pharma Sciences and Research. 2016 Feb;7(2):97–106.

I M C R REV ARTICLE

- 12. World Health Organization. Legal status of traditional medicine and complementary.
- van Staden AM, Joubert G. Interest in and willingness to use complementary, alternative and traditional medicine among academic and administrative university staff in Bloemfontein, South Africa. African Journal of Traditional, Complementary and Alternative Medicines. 2014 Oct 27;11(5):61–6.
- Mousavi T, Nikfar S, Abdollahi M. Comprehensive study on the administrative, economic, regional, and regulatory prospects of complementary and alternative medicine (CAM) in inflammatory bowel disease (IBD). Expert Review of Clinical Pharmacology. 2021 Jul 3;14(7):865–88.
- 15. Payyappallimana U. Role of traditional medicine in primary health care: an overview of perspectives and challenging.
- World Health Organization. WHO medicines strategy 2004–2007: countries at the core. World Health Organization; 2004.
- Balkrishna A, Mishra RK, Srivastava A, Joshi B, Marde R, Prajapati UB. Ancient Indian rishi's (Sages) knowledge of botany and medicinal plants since Vedic period was much older than the period of Theophrastus, A case study-who was the actual father of botany? International Journal of Unani and Integrative Medicine. 2019;3(3): 40-4.
- Shankar D, Patwardhan B. AYUSH for New India: Vision and strategy. Journal of Ayurveda and integrative medicine. 2017 Jul;8(3):137.
- Rahman SZ. Concept of Materiovigilance and Importance in AYUSH. Journal of Pharmacovigilance and Drug Safety. 2020 Dec 31;17(2): 10–4.
- van Staden AM, Joubert G. Interest in and willingness to use complementary, alternative and traditional medicine among academic and administrative university staff in Bloemfontein, South Africa. African Journal of Traditional, Complementary and Alternative Medicines. 2014 Oct 27;11(5):61–6.
- Fakkham S, Sirithanawutichi T, Jarupoonpol V, Homjumpa P, Bunalesnirunltr M. The integration of the applied Thai traditional medicine into hospitals of the current health delivery system: The development of an administrative/management model. Journal of the Medical Association of Thailand. 2012 Aug 3;95(2):257.
- Fong HH. Integration of herbal medicine into modern medical practices: issues and prospects. Integrative cancer therapies. 2002 Sep;1(3): 287–93.
- Nahin RL, Straus SE. Research into complementary and alternative medicine: problems and potential. Bmj. 2001 Jan 20;322(7279):161–4.
- 24. Vitetta L, Butcher B, Dal Forno S, Vitetta G, Nikov T, Hall S, Steels E. A Double-Blind Randomized Placebo-Controlled Study Assessing the Safety, Tolerability and Efficacy of a Herbal Medicine Containing Pycnogenol

Combined with Papain and Aloe vera in the Prevention and Management of Pre-Diabetes. Medicines. 2020 Apr 22;7(4):22.

- Astin JA. Why patients use alternative medicine: results of a national study. jama. 1998 May 20;279(19):1548–53.
- 26. Kew Y, Chia YL, Lai SM, Chong KY, Ho XL, Liew DW, Moy FM, Selvarajah S. Traditional and complementary medicine (TCM) among study population with cardiovascular risk; use and substitution for conventional medicine in Pahang, Malaysia. Med J Malaysia. 2015 Apr 1;70(2):86–92.
- Balaji R, Ramanathan M, Bhavanani AB, Ranganadin P, Balachandran K. Effectiveness of adjuvant yoga therapy in diabetic lung: A randomized control trial. International journal of Yoga. 2019 May;12(2):96.
- 28. Dhungana RR, Pedisic Z, Joshi S, Khanal MK, Kalauni OP, Shakya A, Bhurtel V, Panthi S, Ramesh Kumar KC, Ghimire B, Pandey AR. Effects of a health worker-led 3-month yoga intervention on blood pressure of hypertensive patients: a randomised controlled multicentre trial in the primary care setting. BMC public health. 2021 Dec;21(1):1–1.
- Jiménez-Medina E, Garcia-Lora A, Paco L, Algarra I, Collado A, Garrido F. A new extract of the plant calendula officinalis produces a dual *in vitro*effect: cytotoxic anti-tumor activity and lymphocyte activation. BMC câncer. 2006 Dec;6(1):1–4.
- Chitre S, Patil S, Chaudhari S, et al. ZingiVir-H, a novel herbo-mineral formulation in moderate SARS-CoV-2 infections: a randomized controlled single-blinded multi-center clinical trial. Phytotherapy Research. 2022;36(1):106–113. https://doi.org/10.1002/ptr.7683
- Press Information Bureau. (2022, May 10). AYUSH 64 found useful in the treatment of mild to moderate COVID-19 infection. Retrieved from https://www.pib.gov.in/PressReleasePage.aspx?PRID=1714815
- 32. Singh S, Yadav A, Singh S, et al. A pilot clinical study of an add-on Ayurvedic formulation containing Tinospora cordifolia and Piper longum in mild to moderate COVID-19. Journal of Ayurveda and Integrative Medicine. 2022;13(1):100–106. https://doi.org/10.1007/s11418-021-01911-y
- WHO South-East Asia | World Health Organization. Available from: https://www.who.int/southeastasia?ua=1
- WHO establishes the Global Centre for Traditional Medicine in India. Available from: https://www.who.int/news/item/25-03-2022-whoestablishes-the-global-centre-for-traditional-medicine-in-india
- Abbott R. Documenting Traditional Medical Knowledge. 2014; Available from: http://www.wipo.int/tk/en/resources/publications.html.
- White JD, O'Keefe BR, Sharma J, Javed G, Nukala V, Ganguly A, et al. India-United States dialogue on traditional medicine: Toward collaborative research and generation of an evidence base. J Glob Oncol. 2018 Mar 1; 2018(4):1–10.
- WHO Traditional Medicine Strategy. 2013; Available from: https://in. search.yahoo.com/search?fr=mcafee&type=E211IN885G0&p=30. +2+0+1+42+0+2+3+WHO+Traditional+Medicine+Strategy.+2013% 3B+Available+from%3A+www.who.int
- Health W, Geneva O. National policy on traditional medicine and regulation of herbal medicines Report of a WHO global survey. 2005;

### Yoga for Control of Progression in the Early Stage of NCDs

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### Pooja Nadholta<sup>1</sup>, Saurabh Kumar<sup>2</sup> and Akshay Anand<sup>1,2,3</sup>

#### **Non-Communicable Diseases**

Non-communicable diseases (NCDs) are diseases or body ailments that cannot be communicated or transferred to another person through physical or biological contact. NCDs pose a greater threat to human society more than communicable diseases. NCDs are challenging to treat and are characterized as chronic. However, some chronic diseases, such as cervical cancer, are caused by viral infections as an exception. These diseases have a prolonged course. NCDs usually have complex etiology, and it is difficult to trace the exact cause of these diseases. NCDs can also be called multi-factorial diseases, that is, they have multiple risk factors. NCDs are challenging to diagnose at the early stages of the disease and are generally diagnosed after causing significant damage and at the late stages of the disease. The disease keeps spreading during the latent period. According to the World Health Organization (WHO), nearly 41 million people succumb to the burden of NCDs. Out of all the global deaths, 74% occur because of NCDs.1

#### **Classification of NCDs**

NCDs are commonly classified as seven types of disorders. These diseases are mostly life-threatening. *Diabetes* is an NCD that mainly occurs as a result of a sedentary lifestyle. Other types of NCDs are chronic respiratory disease, cancer, cardiovascular disorders (such as stroke and coronary heart disease), musculoskeletal disorders (such as amyotrophic lateral sclerosis and multiple sclerosis)/arthritis, chronic neurological disorders, and unintentional injuries because of certain accidents that result in permanent physical or mental disabilities (Figure 1).

#### Status of NCDs in India

It is estimated that chronic NCDs are India's leading cause of death. Despite the lack of standard methods to estimate NCD

data, according to the Sample Registration System (SRS-1998), approximately 32% of deaths are caused by these diseases.<sup>2</sup> A series of chronic diseases (chronic disease 3) reported by Reddy et al. estimates deaths (53%) and disabilityadjusted life years (44%) due to chronic diseases. It has been reported that there is a 3%-4% prevalence of cardiovascular diseases in rural regions and 8%-10% in urban areas. Data from six cancer centers of the ICMR has reported approximately 800,000 new cancer cases every year.<sup>3</sup> India consists of the largest number of people with diabetes, which was estimated at 19.3 million in 1995 and is estimated to be 57.2 million by the year 2025.4 Hypertension is also increasing among the Indian population drastically, which is a risk factor for many other cardiovascular and coronary diseases. A high prevalence of hypertension among urban adults was reported from 1995 to 2000, which was 30%-37% in Jaipur, 44%-45% in Mumbai, 31%–36% in Thiruvanthapuram, 17%–24% in Rajasthan, 4.5% in Harvana, and 14% in Chennai. Polling of epidemiological studies showed that the prevalence of hypertension was higher, approximately 25% in urban areas and 10% among the rural population. In the ICMR study, hypertension and inactivity were found to be higher in both males and females in urban areas compared to rural areas in Tamil Nadu, Jharkhand, Chandigarh, and Maharashtra.5 It should be noted that this data is an approximation, and the actual number may be higher than this, as indicated by the

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Figure 1. Classification of NCDs.

growing demand for healthcare professionals, hospitals, and allopathy-based treatments.

#### **Economic Burden**

Besides individual behavior and lifestyle modifications, several other factors, like economic, social, and political approaches, also act as critical factors for NCDs.6-8 NCDs are more prevalent in developed nations. In comparison, developing nations with middle- and low-income economies face a major challenge as the numbers continue to increase. The low-income economy is directly related to poor health status, which contributes to unhealthy food consumption and expensive treatments. NCDs pose a significant economic burden on the growth and development of a nation. As per the WHO estimates, the average pocket expenditure in India, called out-of pocket expenditure for NCDs, is higher than that in other developing nations. The rate of hospitalization increased from 36.3% (in rural areas) to 43.9% (in urban areas) between 2014 and 2017-2018. During this period, the hospitalization cost due to NCDs also increased by ₹4461. In 2017, 81% of the population in urban areas and 86% of the population in rural areas were covered under different health schemes. There are already several government programs running for the prevention and control of NCDs. The 2017 recommendations by the National Health Policy proposed increasing the expenditure from 1.15% to 2.5% of GDP by 2025.9

#### Management of NCDs

According to WHO, around 41 million people lose their lives due to these NCDs annually, equivalent to almost 71% of all global deaths.<sup>1</sup> The critical strategy for reducing the global concern is adequate prevention and related strategies as well as better management. The critical components of management include screening, detection, and treatment. The accessibility of available resources to palliative care for the needy is essential. The primary healthcare system can be strengthened, and timely treatment can be delivered. Reducing the use of modifiable risk factors, like alcohol, tobacco, and unhealthy diets. Also, a lifestyle change, like adopting a balanced diet and engaging in regular physical activity, can reduce the risk. It can significantly prevent NCDs.

#### Control of NCDs Through Yoga

As a traditional form of practice, yoga benefits the human body by encouraging physiological and psychological wellbeing, as well as preventing the development of NCDs.<sup>10</sup> Yoga can be incorporated as part of a daily lifestyle routine to overcome sedentary lifestyles, one of the main contributors to NCDs. The importance of physical activity for a healthy lifestyle is highlighted in the Global Action Plan on Physical Activity (GAPPA) 2018–2030 with a tagline of "more active people for a healthier world". They set a target to reduce physical inactivity by at least 15% by the end of 2030 by implementing policies and plans within a period of 12 years. Dance, Yoga, and Tai Chai, along with walking, cycling, and other sports, if done regularly and at a particular intensity, have been recommended by GAPPA for being physically active throughout the day.11 With the advancement in technology, transportation, economic development, and urbanization, the rate of physical inactivity also increases as lifestyle habits, whether at work or home, become more sedentary. Yoga is the most diverse form of physical activity where not only skeletal muscles but also smooth muscles are involved at different intensities, which can be customized as per an individual's requirements. Similar or different yoga poses and practices can be practiced by adolescents, adults, and the elderly with varying frequencies from beginning to advance as per their body form and type.

An unhealthy lifestyle, which is the leading cause of the development and progression of NCDs, is a result of both physical inactivity and an unhealthy diet, the prevalence of which is increasing with time. Ashtanga Yoga, a concept given by Rishi Patanjali, includes eight components generally known as limbs of yoga, which make a perfect recipe for a healthy lifestyle if followed conventionally. These components are Yama-restraint, Nivamaobservances, Asana-postures, Pranayama-breathing, Pratyaharasenses withdrawal, Dharana-concentration, Dhvana-meditation, and Samadhi-absorption.<sup>12</sup> Most NCDs are preventable, and these aspects of yoga can help build a strong foundation for the body and mind, which can further prevent many lifestyle disorders, including NCDs, from occurring. One of the crucial ways to reduce the death rate due to NCDs is by controlling the risk factors, which include an inactive lifestyle and consumption of unhealthy food, both of which can be attained by practicing Ashtanga yoga, as discussed previously in the text. Yoga is not only cost-effective but also a feasible form of exercise for individuals of all ages.

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It can potentially reduce the risk factors responsible for the development of NCDs, such as obesity, impaired glucose metabolism, psychological imbalance, high cholesterol levels, and blood pressure. More strategies are required for risk reduction, prevention, and progression of NCDs, which support healthy aging and lower the premature death rate caused by NCDs. There is a lack of effective treatment for most NCDs, and management is also costly, contributing to the increased economic and global disease burden.<sup>13</sup> Being healthy (mentally and physically) prevents the body from becoming a suitable target for NCDs. Different dimensions of mental and physical wellness can be achieved by yoga as follows:

- 1. *Asanas Asanas* are body postures where the body holds specific positions for some duration to increase muscle strength, endurance, and stimulation of organs by increasing blood flow to a particular part of the body.
- 2. *Pranayama—Pranayama* is a regulated, controlled breathing technique to increase lung capacity and harmony.
- 3. *Dhayana—Dhayana* is meditation for increasing self-awareness and controlling thoughts.

Yoga affects different systematic axes of the body. The pronounced effect of yoga is to decrease the activity of the HPA axis, which gets activated during stress and adverse conditions.14 The pranayama practice also shows the potential of yoga in regulating heart rate and the cardiac axis.<sup>15</sup> The psycho-neuro-immune axis is involved in immune systemrelated functions such as inflammation and mind-body communication. Yoga helps normalize biomarkers of the neuro-immune axis not only at the molecular level but also at the genetic level.<sup>16</sup> Metabolic syndrome (MetS) is a cluster of risk factors for most NCDs, such as higher blood pressure levels, increased fasting glucose and triglycerides, central obesity, and a low level of HDL. The Ghrelin axis, which gets upregulated in MetS, has been shown to get modulated after the practice of yoga.<sup>17</sup> Therefore, based on the above evidence, it can be said that the yoga practice can achieve a standard concept of health and a healthy lifestyle.

#### Implementation Strategies

The biggest hurdle in implementing strategies and their acceptance among the population after implementation is the need for more evidence-based research. More evidence provides a solid foundation for its implementation. Following are a few preparatory steps that can be kept in mind during the implementation of yoga as complementary and alternative medicine in different policies.

1. *Generating More Evidence*—Without the available evidence, profound research, and action plan, it is neither safe nor feasible to implement any new

strategy (rule, medicine, intervention, and education system). Therefore, the first step in implementing new policies should focus on generating more reproducible, evidence-based research. It can be done by providing resources to the institutes involved in the particular field of interest and providing more financial support, infrastructure, and other required facilities. Besides, quality research should be assured by following good laboratory practices (GLP) so that the evidence produced is reliable and can be implemented.<sup>18</sup>

- Training of Tutors and Educating Children-A 2. special policy can be made for the training of tutors where teachers are trained in yoga and related techniques, including the benefits, practices, and adaptations in daily routine to make it a lifestyle. It will not only spread awareness, but most of the children will also learn about yoga at a very young age. This will add more value to education and, at the same time, increase awareness at a very early stage of life, which will act as a preventive tool for most lifestyle disorders. Also, even if resources are available, people need to be made aware of the importance of the resources. Therefore, raising awareness at an early stage with the right mentors (teachers at the school and college levels) can make a big difference.
- 3. *Awareness*—Unless people are themselves aware and experienced, awareness cannot be spread. There is no reason why yoga cannot be included as a compulsory subject in all educational systems, regardless of whether they are medical or not. The main reason is that medical students who practice medicine can practice yoga, which should be integrated into their curriculum.

The steps mentioned above are of primary importance at the start of an implementation process. Several other steps should be taken before a strategy is planned and can be implemented in all sectors to benefit most of the population.

# Status and Potential of Yoga in the Healthcare System in India

A majority of the Indian population lives an unhealthy lifestyle. It is exposed to the risk factors associated with NCDs. Middleincome countries with limited health professionals tend to have a higher prevalence of NCDs, which are not diagnosed at preor early disease stages, which places a heavy burden on health systems. Other than allopathy, the AYUSH healthcare system of Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy is being practiced in different parts of India. The AYUSH system of indigenous medicine is not only involved in the treatment but also focuses more on preventive approaches. AYUSH was started by a national rural health mission to help solve the shortage of human resources in the available

		Research	Study	Sample	
S. No.	Condition	Institute	Туре	Size	Region
Ι.	Diabetes and pre-diabetes	SVYASA, Bengaluru	Non-randomized controlled trial	896	Karnataka, Maharashtra, Gujarat, Rajasthan, and Tamil Nādu <sup>24</sup>
2.	Healthy individuals	Patanjali Research Foundation, Haridwar, Uttarakhand	A cross-sectional survey	3135	North-western state of Rajasthan <sup>25</sup>
3.	Pre-diabetic and Type 2 diabetes	Regional Ayurveda Research Insti- tute for Infectious Diseases, Patna	Multi-centric, open-labeled study	3044	Bihar <sup>26</sup>
4.	Pain, anxiety, and de- pression in chronic low back pain	SVYASA, Bengaluru	Randomized con- trol, single-blind active study	80	Bengaluru <sup>27</sup>
5.	Pre-diabetes	Srinivas Institute of Medical Science and Research Centre, Mangalore	Randomized- controlled trial	29	Mangalore, Karnataka <sup>28</sup>
6.	Cognitive function: pre-dementia	NIMHANS, Bengaluru	Single-blind con- trolled study	87	Bengaluru <sup>29</sup>
7.	Digestive health and sleep	SVYASA, Bengaluru	Randomized- controlled trial	96	Bengaluru <sup>30</sup>
8.	Age-related changes in healthy individuals	Defence Institute of Physiology and Allied Sciences (DIPAS), New Delhi	Randomized- controlled trial	104	New Delhi <sup>31</sup>
9.	Mild cognitive impairment	SVYASA, Bengaluru	Non-randomized- controlled trial.	88	Bengaluru <sup>32</sup>

Table 1. List of Evidence-Based Yoga Studies.

healthcare system.<sup>19</sup> The shortage of healthcare professionals can be solved by providing more human resources and promoting a preventive healthcare system through AYUSH personnel, which will spread awareness among people about lifestyle management and ultimately decrease the prevalence of disorders.<sup>20</sup>

By preventing NCDs and risk factors with yoga, alternative medicine can potentially reduce the number of patients and the burden on healthcare systems.<sup>21</sup> The government of India designed various strategies for mainstreaming the AYUSH system into the existing healthcare system in the country. These strategies include the integration of the Indian system of medicine and homeopathy with the existing healthcare system, establishment of various centers of Indian system medicine, quality research in this field focusing on standardization of interventional research, advocacy for AYUSH, and establishing links of AYUSH in different sectors.<sup>22</sup> AYUSH mainstreaming is still in progress among the general population, but to make this healthcare system available and accessible for all, there is a need for stringent strategies and implementation, along with a robust monitoring mechanism.23

#### Status of Yoga-based Research in India

After the government established resources for yoga-based research, various institutes started producing evidence using different research study designs on varied populations. Some of the studies are given in Table 1.

India has many institutes where research related to effect of yoga on different health conditions and its efficacy as a preventive intervention is being explored. There is a need for new strategies to implement and policies that can spread more awareness and acceptance among the population for the acceptance of Yoga as a preventive and therapeutic intervention for NCDs.

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#### References

 WHO. Noncommunicable diseases. Retrieved on October 5, 2022 from: https://www.who.int/news-room/fact-sheets/detail/ noncommunicable-diseases

- Nongkynrih B, Patro BK, Pandav CS. Current status of communicable and non-communicable diseases in India. J Assoc Physicians India 2004; 52: 118–123.
- 3. Reddy KS, Shah B, Varghese C, et al. Responding to the threat of chronic diseases in India. *Lancet* 2005; *366*: 1744–1749.
- King H, Aubert RE, Herman WH. Global burden of diabetes, 1995–2025: prevalence, numerical estimates, and projections. *Diabetes Care* 1998; 21: 1414–1431.
- Nethan S, Sinha D, Mehrotra R. Non communicable disease risk factors and their trends in India. *Asian Pac J Cancer Prev* 2017; 18: 2005–2010.
- Yang JS, Mamudu HM, John R. Incorporating a structural approach to reducing the burden of non-communicable diseases. *Glob Health* 2018; 14: 66.
- Krieger N. Theories for social epidemiology in the 21st century: An ecosocial perspective. *Int J Epidemiol* 2001; *30*: 668–677.
- 8. Budreviciute A, Damiati S, Sabir DK, et al. Management and prevention strategies for non-communicable diseases (NCDs) and their risk factors. *Front Public Health* 2020; *8*: 574111.
- Verma VR, Kumar P, Dash U. Assessing the household economic burden of non-communicable diseases in India: Evidence from repeated cross-sectional surveys. *BMC Public Health* 2021; 21: 881.
- Nagarathna R, Kumar S, Anand A, et al. Effectiveness of yoga lifestyle on lipid metabolism in a vulnerable population—A community based multicenter randomized controlled trial. *Medicines* 2021; 8(7): 37.
- WHO. Global action plan on physical activity 2018-2030: More active people for a healthier world. Retrieved on October 5, 2022 from: https://apps.who.int/iris/handle/10665/272722
- 12. Dass BH. Ashtanga yoga primer. Sri Rama Publishing; 2019.
- Peters R, Ee N, Peters J, et al. Common risk factors for major non communicable disease, a systematic overview of reviews and commentary: The implied potential for targeted risk reduction. *Ther Adv Chronic Dis* 2019; *10*: 2040622319880392.
- Aggarwal A. Hypothalamo-pituitary-adrenal axis and brain during stress, yoga and meditation. *IJHCR* 2020; 3(9): 96–103.
- Mohan M, Saravanane C, Surange SG, et al. Effect of yoga type breathing on heart rate and cardiac axis of normal subjects. *Indian J Physiol Pharmacol* 1986; 30: 335–340.
- 16. Gautam S, Kumar M, Kumar U, et al. Effect of an 8-week yoga-based lifestyle intervention on psycho-neuro-immune axis, disease activity, and perceived quality of life in rheumatoid arthritis patients: A randomized controlled trial. *Front Psychol* 2020; *11*: 2259.
- 17. Yu AP, Ugwu FN, Tam BT, et al. One year of yoga training alters ghrelin axis in centrally obese adults with metabolic syndrome. *Front Physiol* 2018: 1321.
- Kumar S, Mehra P, Anand A. Policy research into quality assessment of published data from medical institutes can increase the authenticity of translation. *Ann Neurosci* 2020; 27(2): 45–46.

- Gopichandran V and Kumar CHS. Mainstreaming AYUSH: An ethical analysis. *Indian J Med Ethics* 2012; 9(4): 270–277.
- Eton DT, Ridgeway JL, Linzer M, et al. Healthcare provider relational quality is associated with better self-management and less treatment burden in people with multiple chronic conditions. *Patient Prefer Adherence* 2017; *11*: 1635–1646.
- Sharma RA, Gupta N, Bijlani RL. Effect of yoga based lifestyle intervention on subjective well-being. *Indian J Physiol Pharmacol* 2008; *52*: 123–131.
- 22. Ministry of Health and Family Welfare. *National rural health mission 2005-2012*. *Mission document*. New Delhi: Government of India; 2005.
- 23. Shrivastava SR, Shrivastava PS, Ramasamy J. Mainstreaming of ayurveda, yoga, naturopathy, unani, siddha, and home-opathy with the health care delivery system in India. *J Tradit Complement Med* 2015; *5*: 116–118.
- Venugopal V, Rathi A, Raghuram N. Effect of short-term yogabased lifestyle intervention on plasma glucose levels in individuals with diabetes and pre-diabetes in the community. *Diabetes Metab Syndr* 2017; 11: S597–S599.
- 25. Telles S, Sharma SK, Chetry D, et al. Benefits and adverse effects associated with yoga practice: A cross-sectional survey from India. *Complement Ther Med* 2021; *57*: 102644.
- 26. Sharma R, Shahi VK, Khanduri S, et al. Effect of ayurveda intervention, lifestyle modification and yoga in prediabetic and type 2 diabetes under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)–AYUSH integration project. *Ayu* 2019; 40: 8–15.
- 27. Tekur P, Nagarathna R, Chametcha S, et al. A comprehensive yoga programs improves pain, anxiety and depression in chronic low back pain patients more than exercise: An RCT. *Complement Ther Med* 2012; *20*: 107–118.
- Hegde SV, Adhikari P, Shetty S, et al. Effect of communitybased yoga intervention on oxidative stress and glycemic parameters in prediabetes: A randomized controlled trial. *Complement Ther Med* 2013; 21: 571–576.
- Hariprasad VR, Koparde V, Sivakumar PT, et al. Randomized clinical trial of yoga-based intervention in residents from elderly homes: Effects on cognitive function. *Indian J Psychiatry* 2013; 55(Suppl 3): S357.
- Ganesh HS, Subramanya P, Udupa V. Role of yoga therapy in improving digestive health and quality of sleep in an elderly population: A randomized controlled trial. *J Bodyw Mov Ther* 2021; 27: 692–697.
- Pal R, Singh SN, Chatterjee A, et al. Age-related changes in cardiovascular system, autonomic functions, and levels of BDNF of healthy active males: Role of yogic practice. *Age* (*Dordr*) 2014; 36: 9683.
- Chobe S, Patra SK, Chobe M, et al. Effect of integrated yoga and ayurveda rasayana on cognitive functions in elderly with mild cognitive impairment. *J Ayurveda Integr Med* 2020; *13*: 10037.

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### Analysis of Radio diagnostic test referrals in government hospitals

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#### **KEY WORDS**

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In any treatment taken by patient, cost is an important dimension. These days, diagnostic tests comprise of a significant part of the health cost borne by patient for the treatment. Catastrophic expenditure is a commonly discussed issue by the health care administration. It is often argued that, outsourcing of the medical diagnostic tests is quite frequent. Daniel et al observed in their research survey that there were so many institutes which were outsourcing the tests. They concluded that it may be due to lack of resources in radiology lab [1]. Therefore, in order to avoid the rush of patients or waiting for a long period of time, patient himself or herself prefers to go outside the medical hospital for the tests. The public discourse is rather focused on how to overcome the capacity deficits in the public health system, rather than consolidating the existing resources and data from huge patient rush. This restricts access to vital health information which is being rapidly lost due to outsourcing of diagnostic tests referred by the hospitals, either due to lobbying by private labs or lack of policy in the matter, or both.

A study showed that private labs carried out clinical mistakes in the tests, showing that there is no one accountable and this may lead to out of pocket expenses of patients [2]. Friedman [3] and Feinberg *et al* [4] have found in a survey carried out that there are some unbearable mistakes found in the outsource laboratory investigation which may further create problem for practicing physicians. In 2015, there were 53 surveys about the cost awareness of surgical items. They reported that most medical officers and doctors were not much aware about the market price of those items.

There is a need for healthy relationship between the diagnostic centers and the hospital administration which may lead to the revenue generation for the hospital. Hospital administration has to be attentive about the time, staff, equipment, space and other patient care related management [5].

For making healthcare affordable, there should be a collaborative policy research about reducing cost, labor and time for the diagnostic tests. Therefore, Indian medical institutes should promote patient cost audit [6]. Such policy proposals can generate data and give rise to new policies which can enable the state and national health ministries to plan programs and evaluate their impact based on inputs from this policy research proposal.

A systemic study can be planned which could be based on inputs, processes and the output. In the input section, we can analyze number of employees like total number of professors, additional professor, assistant professors, senior residents, junior residents, lab technicians, nurses and class IV and their combined salary. This may include the number of machines or equipment's and their maintenance charges combined together.

A retrospective study can be subsequently carried out by combining 1 year record from radiodiagnostics for the number of tests done, revenue generated, man power and expenses incurred by the department for maintenance from the annual report record sheets. Prospective study can also be carried out as follow-up study. The parameters which are responsible for delay in radiological tests include date of advice for the test and date on which the tests have been conducted. Also, this could help assess delay, pricing, and satisfaction levels of the tests carried out.

### References

- Altman, D.J. and R.B. Gunderman, Outsourcing: a primer for radiologists. J Am Coll Radiol, 2008;5(8);893–9.
- Chasin, B.S., S.P. Elliott, and S.A. Klotz, *Medical Errors Arising from Out-sourcing Laboratory and Radiology Services*. The American Journal of Medicine, 2007;120(9);819.e9–819.e11.
- Friedman, B., Value based healthcare will drive outsourcing of hospital diagnostic services. Lab Soft News, 2016.
- Pros and cons of outsourcing laboratory services. Journal of oncology practice, 2006;2(4):162–163.
- Mrak, R.E., T.G. Parslow, and J.E. Tomaszewski, Outsourcing of Academic Clinical Laboratories: Experiences and Lessons From the Association of Pathology Chairs Laboratory Outsourcing Survey. Academic pathology, 2018;5:2374289518765435-2374289518765435.
- Anand, A., need for innovation in medical institutions. Annals of neurosciences, 2014;21(1):1–2.

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### Whose Duty Is it Anyway?

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The recent article from Nature emphasizes the need for research in the AYUSH system, suggesting mild COVID patients as cohorts for RCT before repurposing is initiated. However, it falls short of identifying whom to address this right question.<sup>1</sup> In order to develop an in-depth understanding of the complex ecosystem of health care in India, the COVID crisis provides an excellent screening tool for evaluating our general approach to disease management. When the COVID-19 pandemic spread across the globe, no sustainable solution was in sight. Therefore, it provided a level playing field for all systems of medicine to be tapped in repurposing potential drugs, preferably by comparative effectiveness. The health managers in India and elsewhere decided to repurpose HCQ as an alternative drug for COVID-19 without conducting any clinical trial. Many research papers were subsequently published showing that the repurposing potential of HCQ was inconsequential, and these were soon retracted.<sup>2</sup> At a time when the uncertainty of pandemic was raging, these managers decided to take the Remdesivir repurposing forward, and the necessary approvals were provided by the Indian Council of Medical Research (ICMR). Despite the failure of HCQ, these agencies continued to pursue the dogmatic approach by again proposing its use for the vulnerable population and health care workers unlike what was suggested for the repurposing of Ayurvedic drugs. In other words, there seems to be one scientific yardstick for the translation of benefits of one health management system, and another for the other. As expected, the Remdesivir experiment failed again and was subsequently removed from the national protocol for COVID-19. At a time when the allopathy had no solution for COVID-19, many questioned if it is meaningful for Ayurveda or other systems

to be repurposed for COVID-19 management as it had far more published scientific data than either HCQ or Remdesivir put together. No one tried to ask this scientific question, yet many frequently asked why the national AYUSH protocol was approved or why other drugs containing Ashwagandha were being used for post-COVID-19 management. The impending failure of Remdesivir, which was "hyped" to generate "hope," looms large. As a result, the drug was sold in the black market at exorbitant prices, causing both fear and panic. It is well known that the shares of this company soared even though the post-surveillance data was not made available to experts. Surprisingly, even the pharmacovigilance data was also not made available. In USA, National Institutes of Health (NIH) is usually involved in regulating their country's treatment protocol in coordination with CDC which includes sero-surveillance. In health emergencies in India, when decisions are to be taken by the health servicing Department, ICMR stepped in and must be held accountable for the finalization of protocols.

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It was after these repeated failures, the Ministry of AYUSH came out with the national protocol soon after the Katoch committee and the AYUSH's interdisciplinary committee cleared the same.3,4 These committees had reviewed and examined the in vitro, in vivo, and clinical studies based on which this decision was taken through due process. ICMR was also a member in approving the national AYUSH protocol. This protocol was recommended for prophylaxis and management of mild COVID patients as well as for post-COVID recovery. No sooner had the protocol been finalized, the Indian Medical Association (IMA, a nonscientific union of doctors) came out with a rejoinder opposing the AYUSH preventive protocol meant to benefit the patients based on their preferences. While the evidence-based medicine needs to be supported by practice-based experience,<sup>5</sup> IMA now calls for a national protest and dissolution of NITI Aayog study groups made to implement an integrative health system in the country.

The bizarre claim of IMA, a union of Indian doctors, calling Indian System of Medicine (ISM) a "placebo" is unfortunate. It smacks of blasphemous collusion with the journal Science that promptly voiced IMA's version as "a fraud on nation" with an alacrity never seen before.<sup>6</sup> This happened within a week of IMA's claims flashing in the Indian media. This has led to many burning questions about the politics of medicine and money. The quality of scientific temper and ethics, often attributable to medical science communication, remain to be addressed. This journal had earlier landed itself in a controversy when an unprecedented political statement was issued by its editor, asking its readers not to vote for Mr Donald Trump in the US presidential elections. It is our considered view that journals should avoid political posturing and instead focus on hard science, than predictive science. Regardless, others argued that IMA is facing flak at the hands of patient support organizations after the Medical Council of India (MCI) was replaced by the National Medical Commission (NMC) and patients' growing preference for the AyurYog version of the public health approach was weighing on them. The recent defamation suit filed by an Ayurveda practitioner claiming AyurYog to be the "mother of modern medicine" is also aligned to this dwindling patient mood.

The perpetuation of dissociation between patent-based knowledge advancement of modern clinical research and indigenous AyurYog has become so pervasive that some medical practitioners have begun to assume that they are the true owners of this medical progress and everything else is a "placebo." India spends a considerable foreign exchange for importing the medical devices, drugs, and technology used by the Indian medical community. The concept of *Atma Nirbhar Bharat* or self-reliant health structure provides them with an opportunity for leadership in the field of traditional or integrative medicine-related knowledge economy. On November 13, 2020, at the proposal of the honorable Indian Prime Minister, Shree Narender Modi, the Secretary General

of the World Health Organization agreed to set up a Global Centre for Traditional Medicine in India. This now provides a unique opportunity to spearhead the global integrative health initiative through multinational clinical trials ensuing seamless knowledge advancement in the field. <sup>7,8</sup>

Based on these developments, we need to ask the right question to ICMR and not AYUSH as to who should be mobilized to undertake biomedical research in this domain of interdisciplinary area where Ayurvedic or Yogic biology framework can provide the answers. Prof Valiathan's idea of collaborative research between Ayurveda and biomedical research requires implementation. In our opinion, scientific research on ISM is a fiduciary responsibility of the Indian scientific and medical community and not just the AYUSH sector. In this context, it is a right question being asked to a wrong person. We are probably barking up the wrong tree. Every national laboratory, especially those belonging to medical institutes and other government-funded institutions, should research AYUSH systems, collectively funded by national agencies. For this, the faculties of AyurYog will need to be installed in these Institutions so that they may identify the relevant clinical questions for research. This may include cost-effectiveness trials. This will ensure that the discoveries from ISM knowledge receive acknowledgement, much like the Nobel prize-winning work of Chinese Prof Tu Youyou. Prof Tu had spearheaded the application of Traditional Chinese Medicine (TMC) at the time of a malaria epidemic in the 1960s. The Chinese Medical Association wholeheartedly supported this as a matter of national pride.9

ISM is in a containment zone with an access to subcritical resources and disjointed from the infrastructure of premier hospitals and medical institutes. In such a hostile environment, the expectation for AYUSH to advance scientifically would be wrong. While TCM has flourished because of Chinese administration bringing the basic scientists and TCM together, India's integrative health research has remained a prisoner of the dominant Western medicine, aided by erstwhile MCI. As MCI has now been replaced by NMC, ISM must be provided with resources and capacity building in order to bridge the chasm.<sup>10</sup>

Even though the USA and many Western countries do not have a long history of traditional medicine and practice, it has been adopted to endorse NIH's focus from "medicine" to "health," much like Indian PM's repeated emphasis on wellness.11 The USA's NIH/National Center for Complementary and Integrative Health model provides a way forward. It has evolved from an Office of Alternative Medicine, once regarded as Senator Harkin's folly and criticized by the scientific community, into National Center for Complementary and Integrative Health. The research capacity in India's health sciences, not just AYUSH, should be taken on priority so that the newly formed working groups of NITI Aayog on integrative health can address the health, wellness, and knowledge economy of India in an evidence-based manner.

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#### References

- Kumar J and Sinha P. Time to bring scientific rigour to the complex challenge of Ayurvedic medicine. https://www.natureasia.com/en/nindia/article/10.1038/nindia.2020.101
- Mehra MR, Desai SS, Ruschitzka F, et al. Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: A multinational registry analysis. Lancet 2020.
- National Clinical Management Protocol based on Ayurveda and Yoga for Management of Covid-19, Ministry of AYUSH, Government of India. https://www.ayush.gov.in/docs/ayush-Protocol-covid-19.pdf
- 4. Golechha M. Time to realise the true potential of Ayurveda against COVID-19. Brain Behav Immun 2020.
- 5. Islam MN. Repackaging ayurveda in post-colonial India: Revival or dilution? S Asia: J S Asian Stud 2012; 35: 503–519.

- Pulla P. 'A fraud on the nation': Critics blast Indian government's promotion of traditional medicine for COVID-19. https://www.sciencemag.org/news/2020/10/fraud-nation-critics-blast-indian-government-s-promotion-traditional-medicinecovid-19
- WHO to set up centre for traditional medicine in India, PM says matter of pride, November 13, 2020, *Hindu*. https://www.thehindu.com/news/national/who-to-set-up-centre-for-traditionalmedicine-in-india/article33091388.ece
- Anand A, Tyagi R, and Kaur P. Incubating integrative medicine in India through PMO's Atal Incubator Scheme of Niti Aayog. Ann Neurosci 2017; 24(3): 131–133.
- Su X-Z and Miller LH. The discovery of artemisinin and the Nobel Prize in physiology or medicine. Sci China Life Sci 2015; 58: 1175–1179.
- Rudra S, Kalra A, Kumar A, et al. Utilization of alternative systems of medicine as health care services in India: Evidence on AYUSH care from NSS 2014. PLoS One 2017; 12 (5): e0176916.
- Sen S and Chakraborty R. Revival, modernization and integration of Indian traditional herbal medicine in clinical practice: Importance, challenges and future. J Tradit Complement Med 2016; 7: 234–244.

# A recipe for Policy research in AYUSH educational and research programs

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#### **KEY WORDS**

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Yoga, Ayurveda, and Siddha represent the ancient science of healthy living originated in India. Some of the oldest texts from around 5000 years back, such as Vedas and Upanishads, provide evidence of such lifestyle. Many seals and fossils from Indus Valley Civilization authenticate the practice of Yoga in ancient India. According to yogic tradition, Shiva, one of the Hindu Gods, is the first yogi (Adi yogi) and the first teacher (Adi Guru). The meticulous practice of Yoga is widely believed to play a major role to overcome mental and physical suffering and leads to self-regulation, and finally to self-realization or liberation. Since the Pre-Vedic period around 2700 B.C., people started practicing Yoga. Later on, Patanjali Maharshi (between 3rd to 6th centuries BC) systematized and codified knowledge of Yoga through his Yoga Sutras. Later, with the help of many sages and masters, Yoga spread through different traditions, lineages and Guru-shishya parampara. Various Yoga schools viz. Jnana, Bhakti, Karma, Raja, Dhyana, Patanjali, Kundalini, Hatha, Laya, Jain, Buddha, Hatha etc. which follow their own practice, principles and tradition. However, they all lead to the same goal. The history of modern Yoga started in 1893 when the Parliament of Religions was held. After that many yogacharya, teachers and practitioners tried to spread Yoga, not only in India but worldwide (1). One of the milestones in the history of Yoga has been the adoption of the International Day of Yoga. The Honorable Prime Minister Sri Narendra Modi addressed the world community on  $27^{\rm th}$  September 2014 in 69 sessions of the United Nations General Assembly (UNGA) (2). The proposal was approved on 11th December 2014 by 193 members of UNGA to establish

21 June as "International Day of Yoga". Six months later after passing the resolution and confirmation to establish IDY, the first IDY held in 2015. Several Yogic events were organized and publicized throughout India as well as abroad and got national and international publicity that Yoga has originated from Indian culture. The essential and pivotal role of Yoga in education, pedagogy, curriculum, as well as clinical research has been realized well across the globe (3). To achieve the same, AYUSH Ministry was established November 9, 2014 [http:// ayush.gov.in) to facilitate research and educational activity in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy. The existence and excellence of Yoga-based researches in the premier Institutes of India is another milestone towards the implementation of yogic sciences in the academic sphere. Several Yoga departments and centers in the premier Institutes and central universities of India, their existence and establishment, is the result of the consultative meeting on Yoga Education in Universities held in Bangalore on 2<sup>nd</sup> January 2016, chaired by the Hon'ble Minister for Human Resource Development in the presence of Vice-Chancellors from Indian universities. It was resolved to set up a Department of Yogic Art and Science in the Universities and constitute a committee on Yoga Education in universities to look into various aspects pertaining to setting up of these Departments. Further, collaborative efforts were made to support Psychology, Philosophy, and Yogic Science at different collaborating organizations, by utilizing their respective expertise, knowledge, resources and infrastructure (https://www.nhp.gov.in/list-of-yogainstitutes\_mtl). The aim of such centers was to understand deeper knowledge of Yoga philosophy and Yoga therapy based on classical Yogic texts. For the last several years, S-VYASA University has been doing research on evidence-based Yoga & its application, to prevent diseases and to promote positive health (https://svyasa.edu.in/Research\_Publications. html). Swami Vivekananda Yoga Anusandhana Samsathana (S-VYASA), established in 1986, is a pioneer Institute in the field of Yoga Research. It is the first and foremost Institute with a broad vision of scientifically evaluating yoga, its applications, and policies led by Dr. H R Nagendra (4).

A tremendous increase in Yoga participation has been reported in the US since 2005. About 30 million people perform Yoga daily to get health benefits (5,6). The increased global interest in Yoga in recent decades could be based on the health-promoting benefits of Yoga. Yoga therapy is evolving rapidly and advocated as a safe and effective intervention by National Health Services (UK) and National Institutes of Health (US) (7-13). A continuous rise in Yoga schools and practitioners is also evident across the globe (5). The science of Yoga and the underlying technology of this mind-body medicine need a more thorough investigation through carefully designed mechanistic and clinical studies. There are many challenges and barriers that hinder the realization of the optimal potential of Yoga in education and Research (14). For example, the current understanding of Yoga is limited as a behavioral therapy or lifestyle intervention (14). Barriers to the practice of Yoga and the knowledge gap in its understanding also serve as the key determinants of the success of Yoga for its successful implementation as public health administration as well as its practical acceptance in the academic sector. Modern lifestyle, occupational pressure, family commitments are a few suggested barriers for Yoga Practice (9).

Many Western medical schools viz. Columbia University, Harvard University, Johns Hopkins University, University of California, Stanford University, and research centers in Europe have rapidly developed centers of excellence in Mind-Body medicine. However there is a lack of active participation of many of the corresponding premier Indian Institutions and Universities. There is an urgent need to evaluate the perceptions and barriers as perceived by the Institutions of National Eminence and their Ethical and Academic committees that belong to the Indian scientific and academic community for successful evaluation of Yoga-based research and educational programs. This can provide a necessary policy framework for evidence-based decisions for Yoga research, barrier and benefits of Yogic practices and identify the knowledge gap in the research and health care fraternity. There is a need to develop policies that promote the participation of the Indian Institutions and Universities that have not shown their active participation in Yoga research so far. An evaluation of Institutions that have been ranked highest in MHRD's National Institutional Ranking Framework (NIRF) (https://www.nirfindia.org/Home) provides a framework to methodologically rank Institutions across the country driven by the overall recommendations by a Core Committee set up by MHRD. This process can aim to assess the performance of the Institutions based on broad parameters that cover "Teaching,

Learning and Resources," "Research and Professional Practices," "Graduation Outcomes," "Outreach and Inclusivity," and "Perception". The active participation of Institutes with high NIRF rankings and inclusion assessment of AYUSH programs in such Institutions along with their Ethical committees would trigger changes that may lead to the adoption of Integrative medicine in such Institutes and utilize the public health potential of AYUSH research conducted since the launch of Ministry of AYUSH. Until new publication characterized by biomarker, animal models and cell culture studies have dominated the life science ranking (15–33).

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#### References

- 1. Certification of yoga professionals guide book, Ministry of AYUSH, Government of India, 2016.
- Bhattacharyya A, Patil NJ, Muninarayana C. "Yoga for promotion of health": conference held on International day of yoga-2015 at Kolar. Journal of Ayurveda and integrative medicine. 2015 Oct;6(4):305.
- Marques CS, Ferreira J, Rodrigues RG, Ferreira M. The contribution of yoga to the entrepreneurial potential of university students: a SEM approach. International Entrepreneurship and Management Journal. 2011 Jun 1;7(2):255–78.
- Nagendra HR, Anand A. Indian PM's evidence based wellness approach inspires politico-scientific activism. Annals of Neurosciences. 2019; 26(1):3.
- McCall MC. In search of yoga: Research trends in a western medical database. Int J Yoga. 2014;7(1):4–8.
- Birdee GS, Legedza AT, Saper RB, Bertisch SM, Eisenberg DM, Phillips RS. Characteristics of yoga users: results of a national survey. Journal of General Internal Medicine. 2008 Oct 1;23(10):1653–8.
- Hoyez AC. The 'world of yoga': the production and reproduction of therapeutic landscapes. Soc Sci Med. 2007 Jul;65(1):112–24.
- Dayananda H, Ilavarasu JV, Rajesh S, Babu N. Barriers in the path of yoga practice: An online survey. Int J Yoga. 2014;7(1):66–71.
- Chu P, Gotink RA, Yeh GY, Goldie SJ, Hunink MM. The effectiveness of yoga in modifying risk factors for cardiovascular disease and metabolic syndrome: A systematic review and meta-analysis of randomized controlled trials. European journal of preventive cardiology. 2016 Feb;23(3):291–307.
- Aljasir B, Bryson M, Al-shehri B. Yoga practice for the management of type II diabetes mellitus in adults: a systematic review. Evidence-Based Complementary and Alternative Medicine. 2010;7(4):399–408.
- 11. Posadzki P, Ernst E. Yoga for asthma? A systematic review of randomized clinical trials. Journal of Asthma. 2011 Aug 1;48(6):632–9.
- Kirkwood G, Rampes H, Tuffrey V, Richardson J, Pilkington K. Yoga for anxiety: a systematic review of the research evidence. British journal of sports medicine. 2005 Dec 1;39(12):884–91.
- Tabish SA. Complementary and Alternative Healthcare: Is it Evidencebased? Int J Health Sci (Qassim). 2008;2(1):5–9.
- Mutalik G, Tillu G, Patwardhan B. AyurYoga, the confluence of healing sciences: A call for global action. J Ayurveda Integr Med. 2019;10(2): 79–80.
- Sharma NK, Gupta A, Prabhakar S, Singh R, Bhatt AK, Anand A. CC chemokine receptor-3 as new target for age-related macular degeneration. Gene. 2013 Jul 1;523(1):106–11.
- Anand A, Banik A, Thakur K, L Masters C. The animal models of dementia and Alzheimer's disease for pre-clinical testing and clinical translation. Current Alzheimer Research. 2012 Nov 1;9(9):1010–29.
- Anand A, Gupta PK, Sharma NK, Prabhakar S. Soluble VEGFR1 (sVEG-FR1) as a novel marker of amyotrophic lateral sclerosis (ALS) in the North Indian ALS patients. European Journal of Neurology. 2012 May;19(5):788–92.

- Goyal K, Koul V, Singh Y, Anand A. Targeted drug delivery to central nervous system (CNS) for the treatment of neurodegenerative disorders: trends and advances. Central Nervous System Agents in Medicinal Chemistry (Formerly Current Medicinal Chemistry-Central Nervous System Agents). 2014 Apr 1;14(1):43–59.
- Kamal Sharma N, Gupta A, Prabhakar S, Singh R, Sharma S, Anand A. Single nucleotide polymorphism and serum levels of VEGFR2 are associated with age related macular degeneration. Current neurovascular research. 2012 Nov 1;9(4):256–65.
- Anand A, Saraf MK, Prabhakar S. Sustained inhibition of brotizolam induced anterograde amnesia by norharmane and retrograde amnesia by l-glutamic acid in mice. Behavioural brain research. 2007 Aug 22;182(1):12–20.
- Anand A, Saraf MK, Prabhakar S. Antiamnesic effect of B. monniera on L-NNA induced amnesia involves calmodulin. Neurochemical research. 2010 Aug 1;35(8):1172–81.
- Singh T, Prabhakar S, Gupta A, Anand A. Recruitment of stem cells into the injured retina after laser injury. Stem cells and development. 2012 Feb 10;21(3):448–54.
- Gupta PK, Prabhakar S, Abburi C, Sharma NK, Anand A. Vascular endothelial growth factor-A and chemokine ligand (CCL2) genes are upregulated in peripheral blood mononuclear cells in Indian amyotrophic lateral sclerosis patients. Journal of neuroinflammation. 2011 Dec 1; 8(1):114.
- Vinish M, Prabhakar S, Khullar M, Verma I, Anand A. Genetic screening reveals high frequency of PARK2 mutations and reduced Parkin expression conferring risk for Parkinsonism in North West India. Journal of Neurology, Neurosurgery & Psychiatry. 2010 Feb 1;81(2):166–70.

- Anand A, Tyagi R, Mohanty M, Goyal M, De Silva KR, Wijekoon N. Dystrophin induced cognitive impairment: mechanisms, models and therapeutic strategies. Annals of neurosciences. 2015 Apr;22(2):108.
- Banik A, Brown RE, Bamburg J, Lahiri DK, Khurana D, Friedland RP, Chen W, Ding Y, Mudher A, Padjen AL, Mukaetova-Ladinska E. Translation of Pre-Clinical Studies into Successful Clinical Trials for Alzheimer's Disease: What are the Roadblocks and How Can They Be Overcome?
  Journal of Alzheimer's Disease. 2015 Jan 1;47(4):815–43.
- Anand A, Sharma NK, Gupta A, Prabhakar S, Sharma SK, Singh R, Gupta PK. Single nucleotide polymorphisms in MCP-1 and its receptor are associated with the risk of age related macular degeneration. PloS one. 2012 Nov 21;7(11):e49905.
- Sharma K, Sharma NK, Anand A. Why AMD is a disease of ageing and not of development: mechanisms and insights. Frontiers in aging neuroscience. 2014 Jul 10;6:151.
- Sharma NK, Gupta A, Prabhakar S, Singh R, Sharma SK, Chen W, Anand A. Association between CFH Y402H polymorphism and age related macular degeneration in North Indian cohort. PloS one. 2013 Jul 29;8(7):e70193.
- Mathur D, Goyal K, Koul V, Anand A. The molecular links of re-emerging therapy: a review of evidence of Brahmi (Bacopa monniera). Frontiers in pharmacology. 2016 Mar 4;7:44.
- Anand A, Thakur K, Gupta PK. ALS and oxidative stress: the neurovascular scenario. Oxidative medicine and cellular longevity. 2013 Oct;2013.
- English D, Sharma NK, Sharma K, Anand A. Neural stem cells—trends and advances. Journal of cellular biochemistry. 2013 Apr;114(4):764–72.
- Sharma NK, Prabhakar S, Gupta A, Singh R, Gupta PK, Gupta PK, Anand A. New biomarker for neovascular age-related macular degeneration: eotaxin-2. DNA and cell biology. 2012 Nov 1;31(11):1618–27.

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# **Policy research into Quality Assessment** of Published Data from Medical Institutes Can Increase the Authenticity of **Translation**

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#### Saurabh Kumar<sup>1</sup>, Priya Mehra<sup>1</sup>, and Akshay Anand<sup>1</sup>

Scientific misconduct in basic and clinical research is increasingly being reported at an alarming rate.<sup>1</sup> According to a study, more than 40% of the researchers that were surveyed were aware of the malpractice but they did not report it. Similarly, a study conducted by Sheehan et al in 2005 reported that 17% authors of clinical trials were aware about their fabricated data.<sup>2</sup> India stands third in queue in terms of highest number of publications after the USA and China.<sup>3</sup> But, it is embarrassing that many scientific researchers have fraudulent publications, and this is supported by huge number of recent cases. It is reported that several papers published in reputed journals contained duplicate, fabricated, or reused images. As of now there are 980 manuscripts from India that have been retracted, out of which 33% was due to plagiarism, and in 13% of the cases image duplication or fabrication was seen4; there were very few out of genuine quest for authorship. According to a report published in *Nature India*, most of the retracted cases in 2017 were reported from India.<sup>4</sup> Recently in 2019, we witnessed about 130 papers published by researchers from CSIR-Indian Institute of Toxicology of Research, Lucknow, which were found to be problematic. Similarly, 31 publications from Central Drug Research Institute, Lucknow, while 35 papers from Bose Institute, Kolkata, were found to be duplicate or manipulated.<sup>5</sup> In some cases, it has been seen that the published work was not approved by the ethical committees. Therefore, the key question is: Why this is happening? What is the need of research misconduct?

Most research labs funded by different funding agencies (DST, DBT, CSIR, ICMR, AYUSH, DAE, etc.) do not maintain raw data after research work is over. In order to overcome these drawbacks, a policy research can be initiated in different Institutes across the country that can validate (a) whether the published work contains ethical clearance statement from the respective ethical committees (clinical trial registered on CTRI), (b) whether the published work is plagiarized or not, (c) whether the results from various funding agencies projects have been acknowledged in the published

manuscripts, (d) whether the published graphs and tables in the manuscripts match with the raw data available. Files/raw data and other project-related work can be reviewed. Editors of the journals can be approached to provide the details of the published work by contacting the academies who run these journals. Additionally, whether the bench work has been carried out according to the Good Laboratory Practice (GLP) guidelines or not can also be assessed.<sup>6</sup>

At the institution level, there are various rules and guidelines for responsible conduct of research.7 This includes ethical orientation and guidance for researcher, instituting plagiarism check before submission, availability of data in the repository system, supervision of research being conducted, data ownership, data retention, and long-term storage in the form of e-copy besides early reporting of any such misconduct, etc. Besides, an assessment of whether administrative actions have been taken by the host parent institute or not can also be documented. This may include retraction of all the published articles, suspension, removal from the particular project, ban on getting future projects or strict supervision on other projects, ban from any future publications, probation, and termination from the Institute. Besides this, the publishing journal itself has strict guidelines (retraction of article, ban from future publication, penalty, etc.) to counter any such misconduct. Despite of having these strict guidelines, there is a lack of nationally organized framework for handling scientific misconduct which makes basic and clinical/ scientific research more susceptible in medical institutes than anywhere else. It is important that the research being

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conducted poses some benefits to the mankind. Therefore, it is important for us to follow GLPs. Any malpractice not only affects those that are directly involved but also poses a threat to science and technology, and humanity in general.

The solution to any such scientific misconduct is the urgent need for quality control. A quality policy at the institutional level is also required for doctoral programs. This can be achieved by introducing methods to render raw data auditable, back-traceable, and verifiable. In this way, efficient working environment can be created. This will enable efficient productivity and instill scientific temperament.<sup>7</sup> This study will enable the funding agency to implement or impose strict sanction on the PI or researcher that undertook such scientific misconduct. Financial benefits, reliable translation to the society, improved products and services are the outcomes of implementation of good research practices.<sup>8</sup> Based on the data generated from such policy research initiatives, funding decisions can be linked to mandatory implementation of GLP guidelines.<sup>9</sup>

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#### References

- Kaushal S, Tyagi R, Banik A, et al. A unique data validation process by internal and external quality assurance system aimed to combat research malpractice. Int J Sci Res 2019; 8 (8): 2277–8179.
- 2. Gupta A. Fraud and misconduct in clinical research: A concern. Perspect Clin Res 2013 Apr-Jun; 4(2): 144–147.
- 3. Malkarnekar G. India is world's third largest producer of scientific articles: Report. *The Economic Times*. 2019.
- 4. Parvatam S. Cleaning up research conduct in India. *Nature India*, 2019.
- Kochhar R. Frauds in Indian scientific research. *The Tribune*. 2019.
- Kumar S, Modgil S, Bammidi S, et al. Allium cepa exerts neuroprotective effect on retinal ganglion cells of pterygopalatine artery (PPA) ligated mice. J Ayurveda Integr Med 2020.
- Medicine JH. Rules and guidelines for responsible conduct of research, https://www.hopkinsmedicine.org/som/faculty/ policies/facultypolicies/responsible\_conduct. html (accessed October 7, 2020).
- Anand A, R Tyagi, and P Kaur. Policy research for assessment of quality assurance practices in skill development of doctoral programs in medical institutes. Ann Neurosci 2017; 24(3): 134.
- 9. Neuroscience Research Lab. *Redefining quality standards in basic research investigations by broadening the purview of GLP*. Chandigarh: Neuroscience Research Lab.

# A Policy Research Framework for Gender-Based Mapping of Research Scholars After Obtaining Fellowships

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#### Manjari Rain<sup>1</sup> and Akshay Anand<sup>1</sup>

Among the 48.6% female population of India,<sup>1</sup> a small number of females are employed and even fewer women go on to become scientists. Moreover, women in higher education lag behind males with respect to acquiring a permanent position and senior status.<sup>2,3</sup>

Women are found less likely to lead research teams, to hold large research grants, and to receive awards, which is evident from a few women recipients of Noble prize in science.<sup>4</sup> One of the probable reasons for this situation is that most women researchers have reduced publication rate than male researchers,5 which decreases the probability and opportunity for women researchers to attain a permanent position and funding. Lower publication rate may arise because of gender bias or fewer women editors and reviewers or because of poor research quality of study. A recent study has highlighted that the reviewers of grants and publications look for broad and positive words such as "novel," "therapy," and "unique," which are commonly used by male researchers.6 While women are less likely to emphasize their research with emphatic words, this could be another reason for lower publication and grant acceptance.

Women also have more social responsibilities than men and are expected to take these responsibilities more seriously.<sup>7</sup> In India, the peer pressure from society and family on women is greater, which ultimately reduces the scientific vigor in women researchers.<sup>8</sup> Thus, women researchers either settle for mediocre science or eventually leave their research career in between or change their field.

The Government of India has scaled up its flagship of *Beti Bachao Beti Padhao Yojana* (save the girl child and educate her) that ensures education to girl child.<sup>9,10</sup> Further, India has reservation and age relaxation policies for women to support them to undertake higher studies and move forward to be independent researchers. More recently, India also introduced supernumerary seats for girls for BTech program in IITs realizing the potential of girls in engineering subjects.<sup>11</sup> Various women-oriented research fellowships are also increasingly being made available to promote women and their skills. However, women tend to discontinue research after doctorate or during doctorate, even though the

number of female research scholars is comparable to male research scholars. A lack of gender diversity has been studied extensively globally or in a specific region, but the question of "women discontinuing research" is still enigmatic.

Therefore, it becomes crucial to investigate the reasons of women discontinuing research and to develop education policies that reduce the chances of dropout. For this, the career path of research scholars could be mapped for 15 years after they have received government fellowships to pursue PhD. The reasons for discontinuing research could be documented based on a questionnaire, thus giving an opportunity to determine the prominent drivers for female career attrition.

Principal investigators from a range of scientific fields from top 10 or more research institutes could be contacted to retrieve information of their alumni career paths for 15 years. The alumni could be further contacted for any specific comments and feedback about factors associated with their career advancement. Such a study can include information for both the genders to evaluate the proportion of men and women discontinuing research and to evaluate the probable reason and its rate among women as well as among men. This proposed study would highlight the approximate time and temporary positions that a researcher requires before settling for a permanent position within and outside India.

Such study will enable us to identify the most common reasons for discontinuing research among female researchers and also among male researchers. The research can provide the necessary policy framework to formulate better schemes to promote research among females in India based on evidence generated from such policy research.

#### **Author Contributions**

Manjari Rain drafted the article. Akshay Anand conceptualized and critically revised the article.

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#### References

- Government of India. Sex ratio of population by census (1901 to 2011). Available at: http://mospi.nic.in/ statistical-year-book-india/2018/171.
- Wolverton M and Gonzales MJ. Career paths of academic deans: non-journal report. 2000. Available at: https://eric. ed.gov/?id=ED442447.
- 3. Sinha UB and Sinha D. Are Indian women scientists victims of the "glass ceiling?" Curr Sci 2011 March 25; 100(6): 837–840.

- Modgil S, Gill R, Sharma VL, et al. Nobel nominations in science: Constraints of the fairer sex. Ann Neurosci 2018; 25(2): 63–79.
- Asmar C. Is there a gendered agenda in academia? The research experience of female and male PhD graduates in Australian universities. Higher Educ 1999 October 1; 38(3): 255–273.
- Jsgsi R and Silver JK. Gender differences in research reporting. BMJ 2019; 367: 16692
- 7. Bal V. Women scientists in India: Nowhere near the glass ceiling. Curr Sci 2005 March 25; 88(6): 872–878.
- Bal V. Why women scientists in India need affirmative action. 2008. Available at: https://www.natureasia.com/en/nindia/ article/10.1038/nindia.2008.322.
- 9. Government of India. *Beti Bachao Beti Padhao Yojana*. Available at: https://wcd.nic.in/bbbp-schemes.
- Anand A. Affordable neurogenetic screening as a powerful tool for beti bachao. Ann Neurosci 2016 October; 23(4): 195.
- Gohain MP. IITs earmark 14% special quota for girls from 2018. *The Times of India* (16 April 2017). Available at: https://timesofindia.indiatimes.com/home/education/entranceexams/iits-earmark-14-special-quota-for-girls-from-2018/ articleshow/58201268.cms

# Policy Research into Mapping of Indian and Chinese Vendors for Supply of Biologicals to Indian Labs

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Reagents play an important role in the life of lab. Without chemicals, antibodies, and reagents, it is impossible to undertake a good research project. Many researchers and institutes use different reagents in clinical, pharmacological, and observational studies using different purchase procedures. Different manufacturers across the world are developing transgenic products, recombinant proteins, and advanced techniques to supply biological products to various research labs. These chemicals are expensive, thus directly affecting the quality and standards of a research project. One of the major drawbacks is the use of reagents from different companies, which directly affects the results as the quality of these chemicals varies. The price of these chemicals may affect the procurement decision which is based on the applicable rules of a participating institution, quality, and service quality. That is why researchers prefer using chemicals, reagents, and kits of high quality which are relatively inexpensive. Thus, chemicals and reagents manufactured for experimental work are expected to be of good quality depending upon the type of the reagent. The most common grading standards for research reagents are reagent grade, laboratory grade, and technical grade, of which the reagent grade is of the highest and the technical grade is of the lowest quality.<sup>1</sup> Sometimes suppliers provide chemicals of expiry date or reagents get expired, directly affecting the results of the experiments. Government e-market is a platform which facilitates the procurement of goods and services by government agencies and ministries. It is considered as e-market place that allows procurement with minimal human interface. Audit plays a major role in purchase management process that validates appropriate use of material to monitor quality, quantity, accuracy, and efficacy of the procurement process besides review of different contracts and contracting processes. Make in India initiative promotes the manufacturing of products related to research; however, there is no database pertaining to indigenous and international vendors based on which an endorsement for indigenous products can be promoted. The

policy research framework by Department of Science and Technology (DST) can generate data which can be collected from various national labs funded by it. Data from Directorate General of Commercial Intelligence and Statistics (DGCIS) database could also be used to obtain statistics regarding the import or export of such chemicals. (The chemicals have been categorized as "frequently, moderately, or rarely used").

Through such policy research initiative, data can be used by the laboratories and institutions to understand not only the correlation between the price range of reagents and the relative outcome of the experiments but also the extent to which the expenditure is made to non-Indian and Indian biologicals, thus providing the necessary information about the need to facilitate indigenous manufacturing. This will also be useful for setting standards for utilization of chemicals by further preventing wastage of time, effort, and funds for such research projects.

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Priya Mera drafted the article. Conceptualization and review of the study was done by Dr. Vipin and Dr. Akshay.

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- Reference
- 1. Demmerle RL, Taebel WA, and Anderson WF. Reagent Grade Chemicals. *Ind Eng Chem* 1950 January; 42(1): 2–12.

# Introducing Health Promoting Orientation in Hospitals: A Desirable Approach in the 21<sup>st</sup> Century

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The role and purpose of hospitals has drastically changed over last two centuries. It is no longer restricted to providing curative services only. As per WHO Ottawa charter, health promotion concept is now being sought to be applied in all spheres of our lives and in all settings including the hospitals. In a Health Promoting Hospital (HPH), the facility design and planning should ensure adequate floor space for beds, safe water supply and sanitation, ventilation, hygienic conditions, hand washing facilities, isolation facilities, regulation of traffic flow, pest control, waste management, waiting facility, disabled friendly facilities. There is also a need to have a balance between functions and aesthetics of hospitals.

As per this concept, the emphasis of hospital care has now shifted from acute to chronic illness; curative to preventive medicine; restorative to comprehensive medicine; inpatient care to outpatient and home care; Individual orientation to community orientation; isolated function to area-wise or regional function; tertiary and secondary to primary health care and from episodic care to total quality care.

This approach can have a major public health impact by improving the quality of hospital care, the dependence of patients and their limiting caretakers on hospital staff, reducing the risk of the community from waste-related infections and above all, improving the health of staff which would eventually reduce absenteeism and enhance their productivity. This shift in perspective will surely yield rich dividends e.g., reduction of length of stay in hospital, reduction in complications, reduction in admission and readmissions. Healthcare professionals in hospitals can also have a lasting impact on influencing the behavior of patients and relatives, who will be more responsive to health advice given in hospitals.

HPH approach will also help in prevention of transmission of hospital acquired infections by

adopting simple measures, e.g., washing of hands by medical/paramedical personnel before and after contacting each patient and specimen. Healthcare workers should receive vaccinations for hepatitis B, tetanus etc. Here, infection control committees may provide a forum for multidisciplinary input and cooperation, and information sharing.

Hospitals are in strong position to be the advocates for health promotion. They represent the main concentration of health service resources, professional skills and medical technology. In western countries, hospitals are increasingly positioning themselves as the leading providers of health promotion services within the community. This is important since even the health field concept entails that health and illness result from the interplay of genetic factors, environment, lifestyle and medical services. In India, this movement is yet to take off.

In this context, it is not out of context to mention that University Grants Commission, India held its 1<sup>st</sup> Round Table National Consultation for formulation of the policy on Health Promoting Universities (HPU) on 28<sup>th</sup> February 2019, in Delhi. The meet highlighted the involvement of universities in addressing the health needs of the community. By 2022, at least 50% of higher educational institutions are expected to implement core principles/ set standards of HPU. Also, emphasis was put on a need to evolve models of Academic Social Responsibility (ASR) and Institutional Social Responsibility (ISR). By implication, broadening of the scope of HPU to Health Promoting Educational Institutions will include medical colleges and apex medical institutions also. This envisages capacity building of students and staff for health promotion within and outside the hospitals. In fact, a good hospital must have a humanizing environment that can contribute positively to the health of patients as well as its staff by offering an atmosphere of safety, security, cleanliness and physical comfort.

The proposed HPH models may include consultations services to be provided for community participations & social interactions (e.g. student clubs).Organization of regular seminars or talks on health promotion may be encouraged with wider participation. So, apart from medical care provision, hospitals may arrange for periodic health check-ups through regular screening of students, staff and visitors.

Since Postgraduate Institute of Medical Education and Research (PGIMER) is an education and research institute, introduction of a concept of HPH can be one of the most cost effective investments it can make to improve the relationships with patients and community members. Of course, simultaneously, it has to retain and nurture the highest standards of service (patient care), education and research.

In fact, this has been pilot tested through the Neuroscience Research Lab of the institute, which has introduced ASR initiatives. Its members are dedicating 2 hours every week in actively cleaning the areas in and around the institute complex for more than 233 weeks now. Their goal was not only to create and sustain cleaner and healthier environment around the Institute but also to bring positive changes among patients, their relatives and people working in the Institute. Their work has resulted in a drastic change in the vicinity of the Institute. A dumping area was changed into a garden. Several dustbins were installed at the pavement where people used to litter the waste on the street. New urinals were also built near the boundary wall of PGIMER. A foot path was made through the lawns to prevent people from walking on grass.

Besides this, the Department of Community Medicine and School of Public Health, PGIMER, Chandigarh is also working towards interdisciplinary collaboration for enhancement of the patient/ caregivers' satisfaction through implementing the concept of 'Patient-Centred Care' in the Institute. Already, our humble contributions on the issue are uploaded on the PGI website (http://pgimer.edu.in/), under the icon of ''Public Forum'', drop down menu in 'patient empowerment' section. Here, our collaborative work on developing patient education material with Obstetrics and Gynecology, Orthopaedic and Surgery departments are summarised.

The Department has also initiated few new concepts like HPU, ASR and ISR within and around the campus since November 1, 2019. The initiative proposes to harness, harvest and nurture the vast unidentified and submerged potential of the students and staff of the department to enhance the image of PGIMER. The proposed venture is based on the fact that, so far, within the Department, the training of students of Master of Public Health and Bachelor of Public Heath was mostly class room based. It is proposed to involve them in practical ASR/ISR activities which will help in improving the institute's image. It is also proposed to develop a plan to enhance the quality of physical, social and mental environment of the institute. Moreover, 1 hour every Saturday has been given to "Open house session " in the Department which is open for all members to provide a platform for exchange of ideas on health related issues among the students, staff and employees.

For maximum output, hospital based health promotion services should be multi-disciplinary. Besides integrating health promotion policy for patients, staff and visitors into its vision, implementation of HPH concept requires strong leadership and commitment at different levels. Hospitals have the unique opportunity to embrace such change so that they can be a centerpiece of a 21<sup>st</sup> century intelligent health system. This level of change requires acceptance by all stakeholders for new values, visions and goals.

#### **References:**

- 1. Vasilescua R, Barnab C, Epurec M and Baicud C. Developing university social responsibility: A model for the challenges of the new civil society. Procedia Social and Behavioral Sciences 2010; 2: 4177–4182.
- 2. Anand A , Banik A, Minhas G et al. Creating a role model for "Academicians" Social Responsibility (ASR) synergizing with *Swachh Bharat Abhiyaan*: A campus hygiene initiative by PGIMER, Chandigarh. Annals of Neurosciences; 2019; 26:75-81
- 3. Singh AJ. Ideology of Health Promotion. In. "Health Promotion: Need for Public Health Activism Vol I ,Singh AJ, Goel S and Kathiresan J.(editors) Germany LAP LAMBERT Academic Publishing,2013.
- 4. Ahuja P K, Gupta AK, JainB, Singh A and. P Bains: Health Promoting Hospitals. In. Singh AJ, Goel S and Kathiresan J.(editors) Health Promotion: Need for Public Health Activism Vol II, Germany LAP LAMBERT Academic Publishing, 2013
- 5. Goel S, Gupta A.K, Singh A.J. Hospital Administration-A Problem Solving Approach. 1st Edition. Elsevier Publishers, India 2014
- Mental health in the workplace. World Health Organization. 2019 [cited 3 December 2019]. Available from: https://www.who.int/mental\_health/in\_the\_workplace/en/

#### INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

# A UNIQUE DATA VALIDATION PROCESS BY INTERNAL AND EXTERNAL QUALITY ASSURANCE SYSTEM AIMED TO COMBAT RESEARCH MALPRACTICE.



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#### ABSTRACT

Research fabrication and data fraud are one of the major concerns worldwide which are rising and evident from increasing number of retractions in peer reviewed Journals. If not checked, this can impact the reputation of a research organisation as well as the costs of translation of research data. In basic research extremely publicized cases of falsification of data have been reported and it is possible, that there are many unreported or undetected cases. In order to improve the quality standards, the validation processes were implemented for data quality at Neuroscience research lab in India for verifying PhD thesis results. Good Laboratory practices could be implicated in every research institute so that data impostures were prevented. We aimed to establish superior data quality by randomly verifying raw data in multiple projects funded by national agencies before publication of results at Neuroscience Research Lab.

#### **KEYWORDS**

Quality Research, GLP, Validation, Neuroscience, Intra-laboratory validation, Standard Operating Procedures, checklist.

#### 1. INTRODUCTION

Since 1976, Good Laboratory Practices were implemented which determined to establish accurate documentation, quality check and undeviating data. GLP was introduced to monitor the compliance of non-clinical safety testing of drugs at first in the USA in order to regulate the generation of fraudulent data and unethical practices(Carson & Dent, 2007). GLP principles were formulated by Organisation of Economic Co-operation and Development [OECD] for global compliance of testing facilities(Kiranmai) but not research facilities.

The evidence based practice were soon acquiring a tremendous amount of significance in research based laboratories where cross sectional studies generate research data which remains non-validated even after publication, due to lack of routine checkups, recall of record maintenance etc. (Wassie, Zeleke, Dachew, & Kebede, 2017). Scientists believe that Good Clinical Laboratory Practice [CGLP] basically ensures compliance to the control of disastrous effects in the field of research and how to implement good science. On the contrary, these systems provide for an evidence based validation of studies to ensure the audit of data thus enhancing the transparency of work. However, in the last 60 years, Research and Development have gained many breakthroughs in instrumentation which may have a positive impact on quality and quantity of research (Jena & Chavan, 2017) as validation improves the scientific quality of data. The case of testing laboratories adopting the implementation of GLP results in the effectiveness of results thus making the patients more confident about the quality of the diagnostics and treatment (Horvath, 2013)

As mentioned above, the basic research investigations were never monitored by the GLP systems or any other alternative quality assurance module (Carson & Dent, 2007). Quality assurance is a challenging task for implementation in research ecosystem for developing countries because it requires consistency, manpower and resources without Institutional incentive for its implementation because the data duplication, plagiarism and cases of data theft are major factors which brought the research from developing countries under the radar. These factors partly prevented the research from developing countries to be published in reputed journals.

The Neuroscience Research Lab at PGIMER, Chandigarh, India [hereafter denoted as NRL] have voluntarily implemented GLP in basic research lab, hitherto never implemented in world, to meet the globally accepted quality standards and in order to bridge the chasm that exists between the quality systems in labs from developing and developed countries. The initial implementation included creation of validation documents, procedures and an independent review mechanism through a quality assurance unit in order to meet the quality requirements of research studies. As a result the facility was recognized by Quality Council of India [QCI] under Research category for this case study "Redefining Quality standard in basic research investigations by broadening the purview of Good Laboratory Practices" (Horvath, 2013) and later "Digital research lab for enhancing capability: Towards skill development and community outreach" (Neuroscience Research Lab & Medical Education and Research, 2016). The recognition of these systems has made it convenient to expand the systems and implement the tools for backtracing the data resulting in a PhD thesis, as a case study.

#### 1.1 Requirement of Thesis validation:

Truthfulness and morality are basic principles of research. Adoption of these principles is important for the development of science and

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community awareness. Any deviations from these ethics are considered fraud or scientific misconduct. We therefore, intended to extend the available GLP module for validation of compliance to data generation scheme of GLP including compilation processes, digitizated storage, data analysis, cost audit and publication through various procedures and modules (fig1). This is consistent with other corporate houses and certain testing labs(Paszko & Turner, 2001)

Equipment like autoclaves, pipettes, water bath, gel doc, microscopes, and refrigerators, PCRs were often validated for adherence to annual calibration and daily use entries as per established norms (Panel, 2012). Whether the process of experimental set up correlates with accurately labelled and periodically adopted Quality Assurance procedures by QA in-charge, was determined along with periodic audits in testing labs(Sickles, 1992). Similarly, the corresponding use of chemical and reagents sample log was verified with proper labelling of reagent bottle used for the purpose, like good labs(Cushman, Cornell, Howard, Bovill, & Tracy, 1995). The documentation of test facility was checked for accuracy. These were evidenced properly and quality assurance whose protocol has been approved by the Study Director.

#### 2.METHODS



Fig 1.Flowchart showing the methods of research data validation

#### 2.1. Validation of documents for Data Acquisition

The documents pertaining to data acquisition, verification and validation were prepared by the PhD students according to the Plan of Thesis, in consultation with the Study Director. The documents were got verified and finally submitted to the Quality Assurance cell(Hancock & Algozzine, 2016). These documents included Standard operating Procedures[SOPs] for each experiment, Data Recording sheets [DRSs] for all experiments, Raw Book, checklists, Monthly Master Schedules [MS] throughout the duration of PhD, Log registers of chemicals used in experiments, indexed PhD result folders, Sample logs for sample used, documents for inventory management, server storage records of digital data etc(Refaeilzadeh, Tang, & Liu, 2016)

#### 2.1.1. DRS [Data Record Sheet]

Data recording sheets were filled for the real time documentation of correctness/deviations as per GLP rules (Haider, 2001). DRS were issued through Quality Assurance [QA] cell for stipulated time duration. In the event of change in the experimental procedures, DRSs were modified with compliance to the QA approval. DRSs were coded as per master coding used in the established GLP module [fig 2]. These DRSs provided an important tool to verify and validate the experimental dates with chemical log sheets and the corresponding experiments. A typical DRS would contain the step by step information regarding the experimental protocol performed regularly/periodically at NRL [fig2]. The DRS also recorded the materials and equipment used in the experiment in order to maintain back traceability of the usage in their respective usage log books as per estab



lished norms (Opara, 2003)

#### Fig.2 Data recording sheet

#### 2.1.2. SOP's [Standard Operating Procedures]

Standard Operating Procedures were documented protocols and the backbone of Good Laboratory Practices. These were periodically used to work for maximum safety and operational efficiency and to reduce the chance of errors(Hartmann-Fritsch, Marino, & Reichmann, 2016) To validate the experiment protocols, the SOPs pertaining to the PhD Thesis plan [fig 3], were formulated by the researchers followed by validation by Study Director. SOPs, for thesis 1 including experimental [Morris water maze, cDNA and RNA synthesis, DNA isolation, ERG, Stem cell isolation, Laser Doppler, Immunohistochemistry, MLPA Plasma isolation, Tunnel assay etc.], academic [Journal club, DC, DDC, Seminar], SOP's for thesis 2 [SNP genotyping, ELISA, Total protein estimation [By Bradford method] linear range, Flow cytometry of mononuclear lymphocytes, DNA isolation, Separation of lymphocytes and serum] and administrative [Ethical clearance, ordering material, Joint grant requirements, accounts] procedures were formulated. Each SOP was master coded as per GLP module by the personnel of the Quality assurance cell. Format of SOP was obtained from SOP of SOPs. Restricted Circulation Photocopying Prohibited



Fig.3 An example of Standard operating procedure generated for a method regularly practiced in the laboratory

#### 2.1.3. Data archiving

In the lab continuous monitoring systems were used for the storage of data with proper coding. The archive storage conditions had been predefined to maintain the integrity and sustainability of data, all environmental monitoring procedures are implemented within archive storage with defined standard operating procedures in the designated area of storage. Access to the archive is only controlled by and restricted to the QA and the Study Director(Crouse, Coverston, & Cychosz, 1998) A researcher had generated a request to the QA to obtain the archived data with a QA log mentioning date and sign at the time of issue and return.

#### 2.1.4. VPN [Virtual Private Network]

Internet access is primarily associated with GLP to access data remotely for analysis and maintaining confidentiality of such data is achieved by VPN which is used in Neuroscience Research Lab for secured networking for remote access, storage and transferring online data(Corti, Van den Eynden, Bishop, & Woollard, 2014; Furht & Escalante, 2010). Each staff and student in Neuroscience Research Lab is assigned a server domain to store the confidential data with the remote access by Principal Investigator. VPN storage locations are also mentioned in the DRS to link the result data to its respective experiment and also for future access. The Firewall internet security is maintained which creates interface between other network and lab network.

#### 3.QUALITYASSURANCE REVIEW

Quality assurance cell was established independently to verify the quality and deviations of procedures providing the support for carrying out the validation processes as cited in various articles(Taylor & Tranter, 1987) In NRL, QA analysis was carried out for every individual by the Quality In Charge at the end of every month which includes experimental details, adherence to self -declared Master Schedules, Purchase benchmarks, Inventories checking etc, as an adaptation to new amendments. The QA report also records the accomplishments and deviation from the Master Schedule and an explanation from the researcher to justify the deviation and include any unfinished work to be assigned into the next master schedule.

#### **3.1 Master Schedules**

Master schedules was working timeline of every individual research scholar typically for a month which was needed to be self-declared before starting of the month to QA under intimation to the Study Director(Evans & Lindsay, 2013). The master schedule helps the researchers to plan their work schedule, book any high work load equipment, if needed and maintain their inventory required for the procedures, in advance and useful for effective planning and efficient

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execution QA evaluated the progress of every staff at the end of every month and made a report of the ongoing things and work which is not completed yet.

#### 3.2 Inventory update

All inventories of lab were divided among the students who look after the usage of every material. Lab materials like reagents, pipettes, and glassware are placed on different shelves and refrigerators. A Concerned student in-charge of the inventory is responsible for proper usage of materials and periodic procurement through wish lists whenever items reach their critical level. Master inventory sheets are placed in the front of every shelf, cabinet and fridge for easy access. It was mandatory to update these sheets quarterly by the responsible student and should thereafter be reviewed by Quality Assurance in charge. These were also used by the validation processes.

#### 3.3 Checklists

Checklists were prepared with lists of do's and don'ts for every task, ranging from seminar presentation to thesis writing, in order to ensure the completeness of the task without unreported deviation. Other examples include checklist for synopsis preparation, synopsis approval, seminar and Journal club presentation, Ethical clearance, manuscript writing etc. It helps to create a system dependent approach(Hooijmans, de Vries, Leenaars, Curfs, & Ritskes-Hoitinga, 2011) which is another media for assessment of adherence profile of a student undergoing validation.

#### 3.4 Log register maintenance

Sustenance use of log registers was mandatory task for every research scholars in the lab to maintain his/her record related to research activities. A log register maintains the record of Journal clubs presented and attended, leave records, literature search records, SOP records, workshops attended, record of personal discussion with PI and lab meeting attended etc. These records help to maintain the progress and evaluation of individual scholar at NRL.

#### 4.MIDTERM REVIEW

In midterm verification Inter and Intra laboratory validations were done quarterly to ensure the efficacy of work. It was done by internal Quality Assurance in charge and outside laboratories like CDFD Hyderabad, India [fig 4].



# Fig 4. Copy of an Intra laboratory validation report for one of the procedures regularly used in the laboratory

#### 4.1 Physical verification

Biannual audit of test facility by physical verification of inventories, sample log, a log book was also carried out by external auditors to verify the GLP compliance of the students. Thus, it was mandatory for every scholar to update all the required data from time to time. Whether these procedures were followed or not it was also not analysed by the person who carried out the validation.

### 5.Validation of acquired and analysed data before Thesis submission

Validation of thesis was done in a curative way to analyse the thesis for its authenticity. A team of students were made by Principle Investigator to cross verify the data and some of the procedures explained above(Herr & Anderson, 2014). The data was analysed on the basis of the following criteria: raw data and excel sheet, patient data to informed consents, Patient details to physical location and amount of sample left and so on.

**5.1.** Checking of Thesis Format –For writing a thesis, a proper protocol with guidelines was followed in a particular sequence which are- Abstract, Introduction, Review of literature Hypothesis, aim, objectives, result, conclusion etc. All these sections were reviewed for adherence to the format.

5.2. Diagram and figures validation- Various graphs and

illustrations, if any, were matched with relevant data which was cross checked to ensure that no irrelevant data was found filed. Citations were cross verified. The figures were closely matched with their respectively recorded DRS copies, raw book entries and VPN data archives to validate their authenticity and accuracy.

**5.3. Socio demographic analyses** – In socio demographic analyses, the telephonic verification was done by calling every individual patient and controls to match his/her data with excel sheet. For example, cross validation of the patient sleeping time, water intake capacity, diet, parent's education level and income etc. were cross checked.

**5.4 Physical verification of samples**-Each sample was verified for its log, proper location, storage and coding to ensure if it was maintained properly and matched patient's details and date of sampling. It was also ensured that it was properly entered in its respective inventory.

**5.5 Sample coding-** Sample coding was carried out to code the sample for blinding and tracing the location and to maintain the sample log. The sample coding of various samples was verified as per established norms (Grant & MacDonald, 1986)

**5.6 Genetic result matching-**The reports of genetic data and mutations of specific genes of patients on excel sheets were cross checked with hard copies. Results obtained from the capillary electrophoresis were also cross verified. Result verification of genetic data of patient with Dystrophin gene and other genes like APP, PSEN was enumerated and matched the hard copies with excel sheets in PhD thesis 1 and in another PhD thesis the same data of patients with Age related macular degeneration were analyzed and matched with hardcopy.

**5.7 Consent form-** Informed consent forms along with audio visual consents, Patient information sheets, Patient records were cross verified for validation along with signatures of witnesses(Paasche-Orlow, Taylor, & Brancati, 2003)

**5.8 DRS [Data Record Sheet]** -All DRS of experiments was cross examined to check if they were filled concurrently with the experiment. The process was done for locating any discrepancy or deviations in the experiment.

**5.9 Neuropsychology of Patients** – Neuropsychological assessment data was cross checked in the patient, control and follow-ups of a particular time period before archiving the data after coding. The data was tallied with attached consent form along with videography record.

**5.10 Genetic result verification** –Result verification of genetic data of patient with Dystrophin gene and other genes like APP, PSEN was enumerated and matched the hard copies with excel sheet.

**5.11. Blinding sheet** – Blinding sheet was prepared during data acquisition and analysis with every set of experiment. We checked if blinding sheets were attached with every data and the same was recorded.

#### 6. RESULTS

A final report was prepared after PhD Thesis validation. The concerned Quality Assurance personnel wrote a GLP compliance statement indicating assurance for the validated data. A final master validation sheet was prepared with proper recommendations for errors.

#### **6.1 Documentation analysis**

The adherence to SOPs, matching of raw data to excel sheets, accuracy of raw data and statistical analysis of the data was done independently by using validation SOP. It was found that indexes were not made. Some discrepancies were found which were recorded and updated as per GLP compliance.

#### 6.2 Telephonic verification of patients

In PhD thesis 1- The data acquisition dates in records were matched with those obtained telephonically by contacting individuals recruited in the study data. The data of 90 male patients with an average age of 10-11 years were telephonically verified. In continuation to the validation process, the socio-demographic data verification was carried out by matching of hard copies with excel sheets corresponding to the telephonically obtained information including water intake, physical status, educational qualification, parents income, ambulation

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age, use of electronic devices, time of Neuropsychology and their follow ups etc. It was reported that 5 of the DMD cases had expired while telephone numbers of 9 patients did not match with records after 4 years of recruitment. Other minor errors were also found in the data which were included in the master validation sheet for further compliance and necessary correction [Fig5].

In PhD thesis 2- 280 AMD patients and 200 controls were recruited in the study. The study consisted of participants [both AMD patients and controls] falling in the age group of 50 and above. During collection of Socio-demographic data, information pertaining to smoking habits, drinking habits, night sleeping hours, physical activity, yoga practice, history of surgery, co-morbidities etc was gathered. To cross validate the collected data, participants were contacted at their telephone numbers given by them during data collection. Patients were again asked similar questions on phone call. Cross-checking was done to match this data with already existing information. In addition, validation exercise also helped in checking whether participants have voluntarily participated in the study or not. A sheet was made enlisting number of patients who attended the call, 12 of them who didn't respond the call and 6 patients had died and 9 patients had invalid contact number [Table1].

#### 6.3 Neuropsychology Record

In PhD thesis1- The Neuropsychology data was validated by preparing name wise patient list. Consent forms of patients attached with forms was checked individually. Consent forms were found to be attached with every questionnaire duly signed by witness.

#### 6.4 Matching of Experimental data

In PhD thesis 2 - The experimental data comprised of ELISA and SNP genotyping data. The results were maintained in form of excel sheet. The samples were matched with raw data; Data recording Sheet [DRS] was checked to verify the validity of experiments [Fig 6].

Table 1 Thesis 2 Validation of various parameters and action take

6 5 Desult Validation and som	nlalagation
0.5 Result valuation and sam	pre location

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Genetic result data was verified by following different steps. All the genetic data [coafflyser report, soft genetics reports] was attached with Neuropsychology data as analysed in Fig 5.

ocatio	n:	Date:	Validation Done By:
5. No	Contents	Validation	Errors
1	Log register	Done	I.Folder maintained I.Index not made Journal club attended not checked Lab meetings not checked from 7.4.17-14.07.17
2	Sample log	Done	1.File maintained properly 2.Index not mentioned
3	SOP's	Done	1. File maintained with index 2. SOP for NP, Socio demographic, SOP for plasma & computational modelling to be created
4	DRS	Done	1.Files lies with sumit sir properly maintained with index
5	Review of literature	Done	1.Folder maintained with index , not updated and scattered for thesis compilation
6	Inform consent	Done	1.Informed consent attached with every NP data

Fig 5.	Thesis-1A	A copy of Maste	r validating	sheet reportin	ng errors
identi	fied in a sch	iolar's thesis da	ta.		

Location-			Date- Validation done by-		
S.No	Content	Validation	Observation and discrepancies	Action taken	
1.	Informed content	Done	Present	Taken further for analysis	
2.	Clinical data (Fundus and OCT)	Done	Some were missing	Asked to procured clinical data from advanced eye centre PGIMER	
з.	Calling patients for verification of content	Done	Not able to contact some patients due to unavailability. Rest matched	Present and accepted	
4.	Socio- demographic proforma analysis	Done	Matched	Present and taker further for analysis	
5.	Physical verification of samples	Done	Present except one	Removed from final analysis	
6.	Data Recording Sheet	Done	Present but 18 were found to be missing	Asked to make DRS	
7.	Standard Operating Procedure	Done	SNP genotyping, ELISA, Total protein estimation by Bradford method, Linear range, Flow cytometry of mononuclear lymphocytes, DNA isolation, Separation of lymphocytes, Serum and Plasma.	File maintained with index and matched	

Fig6. Thesis 2- Master validating sheet reporting errors and action taken identified in a scholar's thesis data

Parameter	According to	Observation	Correction made	Outcome
	concerned person			
Calling	All the participants	Some patients didn't pick	Consent forms were checked for voluntary	Finally those
patients	had voluntarily	up the phone some were	participation of patients and it was made	participants were
	participated and socio-	dead but for those we	sure that those forms had signature of	recruited who had
	demographic data was	were able to talk Socio-	participants	matched socio-
	correctly entered	demographic data entered		demographic data or
		was correct		signed consent forms
Physical verification of	All samples recruited	Sample 259 not found	Wrong data entered by mistake was	Samples except 259
samples	in study are physically		removed	was included
	present			
Clinical data matching	Clinical data record	Clinical data record of	Asked to procure clinical records	Patients recruited only
	was maintained	some patients was		after getting clinical
		missing		records
Consent form matching	All consent forms	Consent forms were	Incompleted	Incompleted
	were present	present but some didn't		
		have signature of PI or		
		Ophthalmologist		
Matching of	Experimental data	Matched	Matched	Matched entries
Experimental data	matches the excel			included
	entries			

#### 7. DISCUSSION

Cross validation of PhD Thesis by recording various parameters like telephonic verification, record of chemical usage with dates of experiments, thesis format, result cross verification, genetic data validation ensured validity and accuracy of the Thesis which was reassuring for both student and the Supervisor. The thesis of both PhD scholars were submitted after all compliances and corrections and Quality practises had been conducted. This instil a sense of responsibility and enhances accountability of data (McLachlan, 2017). Error reporting at the time of thesis validation, after following Quality practices, enhances the translation value of the research without further need to repeat experiments. Good Laboratory Practices and such Quality checks necessitate the research scholars to maintain the records including sample logs, master sample location chart etc. Format checking of Thesis showed the occurrence of proper algorithm which also reduces the time taken by supervisor to ensure minimising the deviations in the GLP compliance. DRSs, however, are a good source of real time deviation identifier along with proof of experimentation and corresponding utilization of chemicals. These are often installed in other establishments to ensure transparency and

increase cost effectiveness(Best & Kahn, 2016). Similarly, master schedules are used to steer the performance of researcher in a planned manner ensuring real time monitoring. Using VPN networks, the working of staff to becomes system dependent thus enhancing efficiency(Kerzner & Kerzner, 2017). Socio-demographic data validation provided a proper record of patients with change in their habits over the time which necessitates follow ups for prospective studies. The critical aspect of Good Laboratory Practices requires proper audits and verifications which is used to empower data accuracy leading to valuable research. It is difficult to state whether this degree of compliance could be found in other labs not following GLP for the sheer reason that no lab in India and perhaps world follows GLP in the research settings(Organization, 2010)

These findings provide support to the current ideas suggesting the benefits of Good Laboratory Practices for the PhD thesis validation. Documentation in research is aimed to maintain the record of research for Quality Assurance thereby addressing of questions that may be asked under the Right to Information, a right given by all Indians constitution. The validated data enables accurate reporting of data

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manuscripts to various Journals, attracting high citations, awards, grants and national projects especially when no lab in the country follows similar benchmarks implemented.

concepts, technological implications, and future prospects. Journal of Food Agriculture and Environment, 1, 101-106.

- 23 Organization, W. H. (2010). Handbook: good laboratory practice (GLP): quality practices for regulated non-clinical research and development: World Health . Organization
- Paasche-Orlow, M. K., Taylor, H. A., & Brancati, F. L. (2003), Readability standards for 24 informed-consent forms as compared with actual readability. New England journal of medicine 348(8) 721-726
- Panel, B. B. R. (2012). Guidelines for safe work practices in human and animal medical diagnostic laboratories. Morbidity and Mortality Weekly Report, 61. Paszko, C., & Turner, E. (2001). Laboratory information management systems: CRC 25. 26
- 27 Refaeilzadeh, P., Tang, L., & Liu, H. (2016). Cross-validation. Encyclopedia of database
- systems, 1-7 Sickles, E. (1992). Quality assurance. How to audit your own mammography practice. 28
- Radiologic Clinics of North America, 30(1), 265-275 29
- Taylor, J. K., & Tranter, R. (1987). Quality assurance of chemical measurements (Vol. 129): Lewis Publishers Chelsea, MI. Wassie, M. A., Zeleke, A. A., Dachew, B. A., & Kebede, M. (2017). Evidence-based 30.
- practice and its associated factors among medical laboratory professionals in West Amhara hospitals, Northwest Ethiopia. International journal of evidence-based healthcare.
- Wright, D. E., Titus, S. L., & Cornelison, J. B. (2008). Mentoring and research 31. misconduct: An analysis of research mentoring in closed ORI cases. Science and Engineering Ethics, 14(3), 323-336.

#### 8. CONCLUSION AND FUTURE PROSPECTS

Today research misconduct and data falsification is a serious threat to the credibility of science. The manipulated research publications can disrupt the basic scientific honesty and can mislead a research group. It may also wrongly extrapolate the data for community. A 2009 report published by the Office of Research Integrity [ORI] of the US Department of Health and Human Services mentioned a large number of research misconduct analysed from opened cases from 2007-08 publications. A majority of the cases were found to be involved with image manipulation(Mayer & Steneck, 2007). A gradual increase with a significant degree of concern of "falsified images" were identified in published articles over a period of 20 years [1989-2008] in a 2 yearly based analysis(Wright, Titus, & Cornelison, 2008). Another ORI report disclosed a case of research misconduct by a research coordinator from Emory University in a NHLBI and NIH funded grant in 2009(Jamieson). It was observed and simultaneously acknowledged by the research coordinator that patient information was fabricated to increase the number of enrolees in the study while they never existed on ground. Such kinds of scientific misconduct must attract severe penalties. There should be a regulation to identify such frauds and a unified approach should be applied for internationalization of data quality as well as authenticity of research data published.

In Medical Institutes, GLP compliance could be crucial aspect of bringing robustness to data especially when data generated in such Institutes in generally considered soft. Thus, it is necessary for the basic scientists to implement the validation protocols for quality thesis outcome. It will reinforce the quality of research data acceptable to the international standards.

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#### **11. REFERENCES**

- Best, J. W., & Kahn, J. V. (2016). Research in education: Pearson Education India. Carson, P. A., & Dent, N. J. (2007). Good clinical, laboratory and manufacturing 2.
- practices: techniques for the QA professional: Royal Society of Chemistry. Corti, L., Van den Eynden, V., Bishop, L., & Woollard, M. (2014). Managing and sharing 3
- research data: a guide to good practice: Sage. 4.
- Crouse, D. D., Coverston, H. G., & Cychosz, J. M. (1998). Archiving file system for data servers in a distributed network environment. In: Google Patents. Cushman, M., Cornell, E. S., Howard, P. R., Bovill, E. G., & Tracy, R. P. (1995). Laboratory methods and quality assurance in the Cardiovascular Health Study. Clinical 5.
- chemistry, 41(2), 264-270. Evans, J. R., & Lindsay, W. M. (2013). Managing for quality and performance 6.
- excellence: Cengage Learning. Furht, B., & Escalante, A. (2010). Handbook of cloud computing (Vol. 3): Springer.
- Grant, D. S., & MacDonald, S. E. (1986). Matching to element and compound samples 8. in pigeons: The role of sample coding. Journal of Experimental Psychology: Animal Behavior Processes, 12(2), 160.
- 9. Haider, S. I. (2001). Pharmaceutical master validation plan: the ultimate guide to FDA, GMP, and GLP compliance: CRC Press 10
- Hancock, D. R., & Algozzine, B. (2016). Doing case study research: A practical guide for beginning researchers: Teachers College Press. Hartmann-Fritsch, F., Marino, D., & Reichmann, E. (2016). About ATMPs, SOPs and 11.
- GMP: the hurdles to produce novel skin grafts for clinical use. Transfusion Medicine and Hemotherapy, 43(5), 344-352.
- Herr, K., & Anderson, G. L. (2014). The action research dissertation: A guide for 12 students and faculty: Sage publications.
- Hooijmans, C. R., de Vries, R., Leenaars, M., Curfs, J., & Ritskes-Hoitinga, M. (2011). 13 Improving planning, design, reporting and scientific quality of animal experiments by using the Gold Standard Publication Checklist, in addition to the ARRIVE guidelines.
- British journal of pharmacology, 162(6), 1259-1260. Horvath, A. R. (2013). From evidence to best practice in laboratory medicine. The Clinical Biochemist Reviews, 34(2), 47. 14
- Jamieson, J. Case Summaries. Office of Research Integrity, 8 15
- Jena, G., & Chavan, S. (2017). Implementation of Good Laboratory Practices (GLP) in 16. basic scientific research: Translating the concept beyond regulatory compliance. Regulatory Toxicology and Pharmacology, 89, 20-25.
- Kerzner, H., & Kerzner, H. R. (2017). Project management: a systems approach to planning, scheduling, and controlling; John Wiley & Sons. 17.
- Kiranmai, G. U. Good Laboratory Practice (GLP). Mayer, T., & Steneck, N. (2007). Final Report to ESF and ORI First World Conference 19
- on Research Integrity: Fostering Responsible Research. Jun, 4, 2010.
- McLachlan, S. (2017). Realism in synthetic data generation: a thesis presented in fulfilment of the requirements for the degree of Master of Philosophy in Science, School 20 of Engineering and Advanced Technology, Massey University, Palmerston North, New Zealand, Massey University,
- Neuroscience Research Lab, D. o. N., Post Graduate Institute of, & Medical Education 21. and Research, C. (2016). Redefining Quality Standards in BasicResearch Investigations by Broadening the Purview of GLP.
- Opara, L. U. (2003). Traceability in agriculture and food supply chain: a review of basic 22.

## Implementing University/Academicians' Social Responsibility Conceptual Framework in Medical Colleges

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### Amarjeet Singh<sup>1</sup>, Akshay Anand<sup>2</sup>, and Nidhi Jaswal<sup>1</sup>

Corporate social responsibility (CSR) concept has its roots in philanthropy. Now, it has become a necessity for a successful business. In 21st century, the focus is upon the ways in which any business, on a voluntary basis, may contribute to sustain the development scenario by proactively participating in solving various society level issues. A crucial CSR dimension is the mode of interaction of enterprises with their staff, clients, community, NGOs, civic authorities, etc. CSR involves the commitment by business enterprises for economic development such that it improves the living standards of the employees as well as their families besides development of neighborhood and the community. CSR is an important tool of value addition in business management, which fulfills its obligation to the societal welfare by protecting the environmental resources affected by its anticipated actions and policies.<sup>1</sup>

This concept has not been incorporated into institutions of learning and thus needs to be applied to academic institutions also, since these are important parts of our society. Universities are, now, expected to contribute constructively to social development transcending all barriers. University Social Responsibility (USR) seeks to develop and strengthen societal commitment. It also encourages active citizenship among the students and the academic staff. Besides their routine academic activities, they need to be encouraged to work for service provision to the neighborhood and to promote commitment for holistic sustainable development with a focus on ecological, environmental aspects. As such, academic institutions have a tremendous potential to give a sense of direction to students and society, enabling them to accord social relevance and kindle societal interest.

Here, universities are expected to be flexible enough to adapt locally and respond to various changes so as to meet the postmodern world challenges. This way, these will be able to catalyze the change dynamics favorably. Universities need to improve the students' involved and dedicated response to the societal needs.

By implication, this concept may also apply to hospitals/ medical colleges, which, so far, were mainly concerned with patient care. They hardly have a direct one to one contact and shape the relationship with the society at large. Being an education and research institute, Postgraduate Institute of Medical Education and Research (PGIMER) caters to a good number of students, fellows, staff, and faculty members. Given its vast reach and captive audience of young students and professionals, introducing a concept of USR/ASR can be one of the most cost effective investments PGIMER can make to improve the relationships with patients and community members while simultaneously retaining and nurturing the highest standards of service, education and research.

One such example of ASR initiative is from the Neuroscience Research Lab of the institute. For more than 233 weeks their volunteers have been dedicating 2 h every week in actively cleaning the areas in and around the institute complex. Their goal was not only to create and sustain cleaner and healthier environment around the institute but also to bring positive changes among people working in the institute, patients and their relatives from northern India who seek treatment at this reputed Institute. Volunteers interact with the weekly assembly, educating them about the importance of hygienic surroundings in preventing diseases. The importance of self-hygiene and clean surroundings is highlighted through demonstration of correct method of hand washing, coughing, and its linkage to prevention of communicable diseases. Their work has motivated onlookers resulting in a drastic change in the vicinity of the institute. A dumping area was changed into a garden. Several dustbins were installed at the pavement where people used to litter the waste on the street. New urinals were also built near the wall of PGIMER with

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the help of volunteers. A foot path was made through the lawns by authorities in order to prevent people from walking on grass after consistent awareness programs focused around this area.<sup>2</sup>

Encouraged by this initiative, the Department of Community Medicine and School of Public Health, PGIMER, Chandigarh have mooted a concept of "Academicians' Social Responsibility" (ASR) and institutional social responsibility (ISR) within and around the campus since November 1, 2019. The SOPs are being worked out under the guidance of Dean (academics) of the institute. The initiative proposes to harness, harvest, and nurture the vast (but so far unutilized) potential of the students and staff of the department for enhancement of the image of PGIMER. The proposed venture is based on the fact that, so far, within the Department, the training of students of Master of Public Health and Bachelor of Public Heath was mostly classroom-based. It is proposed to involve them in practical ASR/ISR activities, which will help in improving PGI's impact. It is also proposed to develop a plan to enhance the quality of physical, social and mental environment of the institute. This venture also includes enhancement of the patient/caregivers' satisfaction through implementing the concept of "patient-centered care" in the institute. Already, our humble contributions on the issue are uploaded on the PGI website, under the icon of "Public Forum," drop down menu in patient empowerment section. Here, our collaborative work with Obstetrics and Gynecology, Orthopedic, and Surgery departments has been summarized.

The whole idea of ASR/ISR is that all of us should not just remain itinerant members of the institute/medical college. We gain knowledge, training, recognition, and our livelihood from the institute. In addition to our assigned tasks, we should also work to develop and promote healthy and sustainable policies and planning throughout the institute for the overall benefit of the society. The moot question is... WHAT WE GIVE BACK to it and to the society. ASR/USR concept will provide the mechanism to do that.

#### References

- 1. Vasilescua R, Barnab C, Epurec M, et al. Developing university social responsibility: a model for the challenges of the new civil society. Procedia Soc Behav Sci 2010; 2: 4177–4182.
- Anand A, Banik A, Minhas G, et al. Creating a role model for "Academicians" Social Responsibility (ASR) synergizing with *Swachh Bharat Abhiyaan*: a campus hygiene initiative by PGIMER, Chandigarh. Ann Neurosci 2019; 26: 75–81.

#### Editorial

## Hope and Hurt of Kashmiri Healthcare

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## **SAGE**

It has been argued in a recent editorial in the BMJ that recent developments in Kashmir may cause problems for welfare and healthcare provisions. However, contrary to such claims, in my view, the recent political changes are not likely to have any effect on the healthcare and well-being of Kashmiris. The Indian parliament approved the complete integration of Kashmir with rest of India to end 70 years of its alienation from the national mainstream. Article 370 of the Indian constitution was temporarily installed in 1947, at the ceding of the semiautonomous Kashmir state to the Indian Union,<sup>1</sup> in order to ensure protection of the native population and their Muslim culture, similar to a few other Indian states. On the other hand, Article 370 provided an opportunity to anti-national forces, particularly those aligned to the bordering country, for the cultural alienation of local people from India. Although the good and bad aspects of Article 370 continue to be debated, but the Indian government felt the need to resolve the problems caused by such alienation of the local people from India, and curb the extent to which this fostered groups that resort to terrorism. Most agree that among other issues, Article 370 promoted discriminatory practices of Muslim men such as annulling marriage by Triple Talaq, money laundering by terrorist sympathizers, and inequitable inheritance of property by local women married to non-Kashmiri spouses. This was due to the inapplicability of Indian secular laws which guaranteed women's rights and allowed for financial audit of state expenditures. Nevertheless, regardless of the political debate and contrary to the views expressed in BMJ's editorial<sup>7</sup> in which concerns were raised about deteriorating healthcare access, revocation of Article 370 will bring a positive change in health infrastructure in Kashmir. The misprojected mental health problems are nothing new in Kashmir and are part of continued stress faced by local men and women living there.<sup>2-4</sup> The recent constitutional amendment is set to empower Kashmir with federally administered free healthcare facilities, obviating the need of Kashmiris to travel up to 24 hrs, often over mountainous terrain, to seek treatment at the Post Graduate Institute of Medical Education and Research, Chandigarh. The revoking of Kashmir's autonomy will ensure equitable access to national resources including the free health and wellness scheme "Ayushman Bharat," in tandem with implementation of other Indian laws like Right to Information (RTI) and the abolition of Triple Talaq. This nationally funded health scheme will provide free treatment of up to Rs 500,000 for each Kashmiri household, besides access to government wellness centers. Because the Indian government has revoked Article 370, the new position will result in increased investments in state's health infrastructure. As part of the scheme, the wellness

centers will be built in each district along with more hospitals and medical institutes. Hence, there is hope that anxiety from cross-border Islamic terrorism and prevailing gender discriminatory laws<sup>5</sup> will be replaced by progress and peaceful co-existence. Therefore, some authors wrongly argue that there is atmosphere of uncertainty which may continue to harm the patients.<sup>6,7</sup> The Indian health and wellness scheme is poised to promote mental wellness among Kashmiris in the manner it has benefitted the 3.5 million Indians who have already availed of this popular scheme. The Kashmir police is geared to ensure not only the access to healthcare but also the voting rights of the Kashmiri people and affirmative action for other minorities. This includes the mental wellness of Pandit communities who had undergone ethnic cleansing at the hands of jehadi forces and will return back to their abandoned Kashmiri homes. Such healthcare model will likely be a role model for the bordering Pakistan Occupied Kashmir.8

#### References

- BBC News. Kashmir: Why India and Pakistan fight over it, https:// www.bbc.com/news/10537286 (accessed 22 August 2019).
- Naik AR. Impact of conflict on mental health with special reference to Kashmir Valley. *Int J Indian Psychol* 2016; 4: 76.
- Médecins Sans Frontières (MSF), The University of Kashmir, Institute of Mental Health and Neurosciences (IMHANS). *Muntazar: Kashmir Mental Health Survey Report*. New Delhi: Médecins Sans Frontières, 2015.
- 4. Bhat RA and Khan SM. Mental health issues in Kashmir valley: An overview. *Arch Ment Health* 2018; 19: 96–96.
- US Department of State. *Country reports on terrorism 2017*. Washington, DC: US Department of State, 2017. https://www.state.gov/wp-content/uploads/2019/04/crt\_2017.pdf (accessed 2 November 2019).
- Horton RC. Fear and uncertainty around Kashmir's future. Lancet 2019; 394: 542.
- Mahase E. Kashmir communications blackout is putting patients at risk, doctors warn. *BMJ* 2019; 366: 15204.
- Kurji Z, Premani ZS and Mithani Y. Analysis of the health care system of Pakistan: Lessons learnt and way forward. *J Ayub Med Coll Abbottabad* 2016; 28: 601–604.

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#### Commentary

## The Case for Academic Social **R**esponsibility

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### The job description of an academic ranges from being an educator, mentor, and innovator to a physician or an engineer. Most academics do not transcend the boundaries of the classroom, lab, or clinic and stay away from contributing towards community development activities unless their field of research or the professional duty takes them to a community or a satellite clinic. The perpetuation of dissociation between professional expertise and community outreach activities was not realized until recently when the honorable PM tried to heighten the civic sense among public on October 2, 2014. He role-modelled by taking his broom to the Delhi streets and began clearing the litter. Soon other senior functionaries followed. He appealed to the public to dedicate 2 hours each week towards community sanitation in an 'ice bucket challenge' fashion, inspiring them to upload the 'before' and 'after' pictures on MyGov.in, Facebook, and so on. He obviously didn't want to specify the academics or their Institutions, on whom lay the great responsibility, but he did challenge the nine important celebrities exhorting them to aim for cleaner India. The Ministry of Science and Technology followed the cue and soon came out with a circular asking the research institutions to engage in social outreach activities. This included teaching kids in socially excluded localities. There were no specific official circulars imploring the academics to undertake any such activity as it was natural to be overwhelmed by the government reminder for aesthetic and cleaner environment. However, institutions, as per official requirement, secured a formal 'pledge' to keep the surroundings clean, undertaken through the heads of organizations. It was immediately taken up to ground zero by the faculty and students of Post Graduate Institute of Medical Education and Research. The responsibility they carry continues unabated. 4.5 years later, when a research paper on the subject was being written, the idea of 'academic social responsibility' was coined by a senior colleague and coauthor so that this activity could inspire others to follow suit as this might be helpful in scaling the practice and consequently curbing the infections related to the lack of sanitation.

## Why Science Educators and Academics **Can Inspire Community Work**

Professionally qualified social workers and other social reformers are often seen working with communities. The science educators and their students are missing from these places, partly because the current research curriculum does not include this important element of soft skill development and partly because they wear a condescending attitude. Since the scientific community is looked upon with awe and respect its role modeling in community development, their role-modelling can scale up the campaign. The experience and eloquence of academics drawn from the Chandigarh institution collaborative group, the CRIKC, can be effectively used to spearhead the public health outreach campaigns for cleaner Chandigarh. This can be done by allocating @2 hrs per week for 'litter pick up' campaigns, led by supervisors and their students. These academics from PGI, Panjab University, NIPER, IISER, IITR, CSIO, GMCH, etc., are best positioned to educate the street gatherings about the importance of hygiene and sanitation, and its link with health and diseases by themselves cleaning the area. This can further escalate the Clean India campaign. A spirit of academic social responsibility can be formally introduced for various PhD programs among CRIKC institutes.

As an example, after the neuroscience professor and his students descended on the streets 4.5 years back, people and patient's attendants spontaneously gathered to listen to them and to follow them in their weekly litter pick-up activities, clicking pictures and at times clearing the litter spread across

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the campus. The campus used to be replete with mud holes, garbage, and scattered plastic bags and plates. In those days, there were not many dustbins or signposts in the campus. When this group of academics descended on the campus streets and wrote to the institute authorities, taking turns for leading the campaign, week after week, the litter comprising food plates, bidis, and *gutkas* disappeared from the campus. The shiny steel signposts and swanky dustbins replaced them. Many research lab heads, students and nursing staff, visiting professors, community heroes, and alumni also joined the campaign in these intervening 4.5 years. Despite blind criticism, coupled with general dislike for litter, the campaign continued uninterrupted, without break. By the time the new director joined, things were in order-the mud holes had been replaced by green lawns, and littered plastic bags by plants, flowers, and signposts. The institute was later also recognized for championing the cause of cleanliness.

## **Butterfly Effect**

A study by research scholars of Panjab University examined the "before" and "after" effects of Clean India activity at PGI. Inspired by the regularity of the students and their supervisor descending to the campus, week after week, and uploading the pictures of activity on MyGov.in, a team from Panjab University carried out a masked survey randomly asking the laymen in the campus about "who were the people" carrying out the litter-pick activity and "what was the impact noticed." They sampled about 100 people and found that there was good awareness among patients and their attendants about this activity. In a population of migrating patients, sustaining the Clean India campaign was more than expected. Slowly, the dustbins began to appear next to various *rehris* (roadside stall) outside the campus. Even the place where daily rationing of langars (community meal) used to be held wore a cleaner look. The area which was full of maggots soon became cleaner and hygienic. A large garbage dumping container was also installed next to the *langar* area by the municipal authorities. The frequently urinated wall outside PGI's Gate No. 1 soon began to appear cleaner. Subsequently, the vendors moved to the adjacent area outside Gate No. 1, accompanied by rebuilding of the bus stop to the other side of the road, further reducing the litter generated. By this time, a professor of PGI had launched a vendor sanitation program. This had a cascade effect in the immediate community as the vendors, who had moved to the adjacent venue. For some time, they began to wear gloves and aprons.

## Change Within

The Clean India campaign brought an invisible transformation in the academic life of participants with

qualitative change in attitude among students and faculty. Most students reported a surging feeling of service and a growing urge to relate their research work to social benefit. Many participants were humbled by the poor who lived on the streets. They were able to appreciate the work done by ragpickers and speak to street gatherings, inspiring them to carry on with a spirit of service and compassion. However, a few continued to be condescending and remained irregular participants in this voluntary scheme. Others agreed that this activity was a great stress buster, especially after a grulling lab experiment had failed. Many even brought their family members and kids on days that marked 50, 100, 150, 200 weeks of Clean India activity. They felt that the interaction of academics with general public boosted their morale and self-confidence, and lent a sense of meaning to life, often amiss in academic life.

#### Challenges and Future Perspectives

ACRIKC charter for mandating academic social responsibility in the research training can enable the institutions to lead the public health initiatives. Academics work in groups and their students are important members of knowledge generation besides driving its translation. The community outreach activities provide the necessary substrate for knowledge translation for social benefit. As students are creative frontrunners of any academic activity, many of them were quick to make weekly outreach rosters to bring structure to this voluntary activity. A few of them published two editions of illustrative comic "Magical Broom" and "Magical Broom Returns" that described personal experiences and challenges from this activity. The sanitation workers felt elated at seeing academics doing their job and appeared more accepted by the intellectual class. A few of them found such outreach activity imposing and often skipped it and later left the group. Even though academics are expected to be cognitively unbiased and evidence-based in their approach, a few remained struck to a certain ideology subtly justifying nonengagement in the litter pick-up campaign. They reasoned that this was the duty of sanitation workers and that it affected their research work. For them, it was a waste of time (@2hrs/week). For those few, this activity had roots in nationalistic or presumably a right wing ideology which they did not adhere to. Ironically, science fails where outreach begins.

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## Narendra Modi's citizen centered Yoga-Diabetes Management Program: Will Indian State install Integrative Medicine in premier Institutes?

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#### **KEY WORDS**

Modi Integrative Medicine Yoga

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More than 30,000 people were trained to perform Yoga with Indian PM at Capitol Complex of Chandigarh last summer. The occasion was, 'International Yoga Day 2016' (IYD). They not only watched their PM, Mr. Narendra Modi performed Yoga but also took his call to translate the Yoga for Diabetes management in letter and spirit. On June 21, 2016, the TV channels remained glued to Capitol Complex as Indian PM descended from the high security stage, entering a special T shirt camouflaged Indo Tibetan Border Police guarded enclosure and began following the Yoga protocol the public suddenly got up to create space for him, duly aided by the local Deputy Commissioner. The Editor experienced the aura of PM in the same enclosure where he performed Yoga with the charismatic Person. PM's announcement of new focus of Yoga from on IYD soon shaped the Ministry of AYUSH sponsored Yoga based Niyantrit Madhumeh Bharat (NMB) campaign (controlled Diabetic India) which has become India's largest politico-scientific enterprise beyond Chandigarh. This discourse was quickly nationalized by none other than PM's Yoga Advisor, Dr H R Nagendra, the Chancellor of Swami Vivekananda Yoga Anusandhan Samsthana (SVYASA) and Vice President of Indian Yoga Association (IYA). More than 2,000 volunteers, academicians, administrators and yoga enthusiasts have joined the 240,000 subject study spread across the country. The project aims at investigate the effects of Diabetic protocol of Yoga in halting the conversion of pre diabetics into Diabetics as well as management of Diabetes in general. Scientists and research scholars are upbeat about undertaking world's biggest study which is statistically powered to explore the horizons of Yogic lifestyle through 3 months of Yoga intervention in a randomly selected prediabetic and Diabetic population of urban and rural India. The protocol of Yoga is devised from ancient knowledge of Indian Yogic tradition. Many senior Gurus have advanced Yoga based popular spiritual schools being run in the country. In a rare brainstorming session in Haridwar, Swami Ramdev was recently elected as the President of IYA in a rare display of cooperation between

the Guru of Art of Living, Sri Sri Ravishankar, Dr H R Nagendra, Dr Joshi, Portugal's Yoga Guru Suryananda Maharaj, Directors and representatives of Ministry of AYUSH. This was artfully facilitated by the Quality Council of India enthrusted with the job. The focus of Yoga on Diabetes has being widely argued as part of the larger goal of installing Integrative Medicine in post modern India where health care costs are escalating. A special commission, called the National Medical Commission, has been set by the Govt of India and is all set to replace the archaic Medical Council of India. The interdisciplinary commission is likely to consider the agenda of Integrative Medicine once the bill is passed by the Indian Parliament. The Govt's goal is to provide Quality healthcare at reduced costs by checking out of pocket expenses of patients and innovation. For diseases that are not curable or non-communicable, Yoga is reemerging as the new health mantra and scientists have suddenly become overbusy analyzing the new scientific evidence emerging from increased funding in Yoga research.

The NMB program has engaged about 1200 Yoga Volunteers for Diabetes Management (YVDM) from 380 locations in India, spanning about 62 districts from various states of India. The Principal Investigator, Dr. R Nagarathna, Director of Arogyadham, SVYASA, is coordinating the Ministry of AYUSH sponsored Yoga intervention program for Diabetics in the country. A special task force consisting of International experts, scientists and voga mastershave drawn up the grand plan. They are currently managing the resources and implementing the project in all major locations in the country. An urban and a rural location in each district has been identified before launching the door to door visits by trained YVDMs. The target of screening 1000 individuals for prediabetics and diabetics and follow up confirmatory blood tests from each of 62 districts is already completed. Yoga protocol is being administered to prediabetics and diabetics by these new doctors (read YVDMs) who are scouting daily attendance diaries for documenting compliance. The early morning health mantra is expected to continue for 3 months. The correspondingly distant localities in the same District constitute as Yoga waitlisted prediabetics/diabetics who might be initiated into Yoga at the time of international Yoga day, 2017. Almost 25-40% of pre-diabetics/diabetics in India have been reportedly discovered so far in the study. This is based on single page questionnaire adapted to the Indian Diabetes Risk Score (IDRS). In an unprecedented citizen driven yoga science project, the volunteers were seen carrying measuring tapes, weighing scales and Xerox copies of questionnaire, frantically knocking at the doors of 240,000 households of India, visiting their homes with enthusiasm, filling up forms and sporting their informed consents. Whatsapp groups became an instant hit among YVDMs and they seamlessly communicated with other counterparts across the country, making science fun and evidence based in rural India. They shared challenges, experiences, resources and pictures of blood camps that went viral on social media. The group leaders are in a hurry trying to accomplish the time bound project, regardless of their individual assignments and exams because the 3 month yoga intervention will end by June 7. This will ensure that the reports from all locations of the country are compiled in time and analyzed before being presented to the Prime Minister just before the International Yoga Day June 21, 2017. Individuals participating in the project are not only excited about the free blood tests but also about becoming a subject that will generate data from their regular Yoga practice 3 months hence. Many individuals in urban localities and some Heads of Departments are uneasy about these scientific efforts. Many argue these as early signs of conflicts between modern and traditional medicine. A large number of population has, however, been identified as carrying the risks for Diabetes. One village is reported to be completely diabetic while some villagers have out rightly rejected it as unimportant scheme as 'they had lived their lives and would rather die than worry about impending Diabetes'. Detailed research papers, case reports with exciting details are likely to flood the Journals after June 2017.

Each day, the pre-diabetic and diabetic individuals await being contacted by phone calls, SMS messages and Whatsapp communication, so that they could assemble at the venue of yoga sessions, admiring the tireless efforts of YVDMs. They appear impressed by the sheer scale and social impact of the project. Each morning, from 5.30–6.30 am people assemble in defined venues, in both rural and urban localities of India, to learn and practice Diabetic Yoga protocol for 1 hr. The average attendance is 80%. The YVDMs are main busy travelling and organizing daily morning camps at multiple locations, making notes, carrying attendance related paraphernalia from one venue to the other so that quality data can be collected, coded and analyzed before International Yoga Day 2017.

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## Creating a role model for "Academicians" Social Responsibility (ASR) synergizing with Swachh Bharat Abhiyaan: A campus hygiene initiative by PGIMER, Chandigarh

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#### **KEY WORDS**

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#### ABSTRACT

**Background:** The state of disarray from unhygienic conditions and excessive litter throughout urban highways, alleyways, and byways across rural and urban localities of India is abysmal. Such unsanitary conditions impinge upon the future health and welfare of its citizens, tourists and economic development.

**Purpose:** The NRL volunteered PGIMER's campus hygiene initiative" is a pioneering effort spearheaded in compliance with Indian Prime Minister's call that citizens of India work together to establish a cleaner and healthier environment.

**Methods:** A group of 15 highly motivated students in the Neuroscience Division of the PGIMER, worked together vigorously 2 hours a week to affect a cleaner urban environment in the city.

**Result:** The results were national *Kayakalp* and *Skoch award* to PGIMER as the cleanest hospital in the country, the vendors or patients no longer litter around the campus, the pot holes have been converted into greener patches, signs board adorn the campus.

Conclusion: To inspire citizens through faculty- student led sanitation programs.

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## Introduction

India is a country of aspiration with the second largest population in the world. After 71 years of independence, India continues to seek solution to sanitation, social, economic and ecological issues. On one hand, it has been defined by World Bank as the largest population of poor in the world [1], on the other hand, it aspires to overtake China as the world's largest economy by the year 2050 [2]. While most of the population lives in poverty and cannot afford a sustainable healthcare, India is emerging up as an Asian epicentre of medical tourism with advanced, low-cost health care system [3]. The poor state of sanitation in the country greatly affects the health of its citizens, especially those living in rural locations [4, 5]. The status of sanitation in India has remained highly neglected for a prolonged period. Studies carried in India and overseas highlight the lack of sanitation as the primary cause responsible for the increased number of enteric diseases like Cholera, Typhoid etc [6, 7]. Appropriate methods need to be adopted as prime objectives in the management of sanitation. Sanitation refers to domestic and personal hygiene and control over the communicable diseases. Preventive health care strategies are required to eradicate the existing problems of sanitation in India which has not been seriously successfully highlighted by successive Governments or academicians in the recent past.

According to NSSO survey, less than 32% rural houses have their own toilets. They highlight the immense inadequacy of sanitation in India. It is believed that around 47% of the

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total population of India practice open defecation which can be the result of poverty and illiteracy [4] and bring the same habits when they visit hospitals 88% of diarrheal diseases are attributed to unsafe water supply, inadequate sanitation, and hygiene. Sanitation interventions including hygiene education and correct method of hand washing which can lead to a reduction of Diarrhoea cases by up to 45% [4]. It is worthwhile to take note of the great awareness campaigns initiated in London in the mid-19th century in order to counter unhygienic issues in their country [8]. Our neighbouring Asian country, Singapore also took up the challenges of cleanliness in 1968 when its first Prime Minister of independent Singapore, Mr. Lee Kuan Yew, initiated the "Keep Singapore Clean" campaign in the island [9]. This was one of the longest campaigns (1968-1990) in the nation whose visible impact on the immediate environment can be seen even today.

Given the deteriorating situation of the country, the newly elected 15<sup>th</sup> Prime Minister of India, Mr. Narendra Modi, on 2<sup>nd</sup> October 2014, on the occasion of the 145<sup>th</sup> birth centenary celebration of 'Mahatma Gandhi' initiated the nationwide Clean India movement under the slogan of "*Swachh Bharat Abhiyaan (SBA)*" [10]. This campaign was a citizencentred public health initiative appealing to the citizens of India to devote 2 hours per week for litter pickup campaign. *SBA* was, therefore, proposed as the mission towards *Clean India* in order to overcome the ill-effects of unhygienic surroundings. A Finance Act 2015 has also recently levied 0.5% *Swachh Bharat* cess on all the taxable items to generate govt funds for sustaining this initiative [11].

On the path set up by Government of India, NRL, PGIMER decided to contribute to this noble mission. They started dedicating 2 hours every week by actively picking up the litter around Institute complex.

#### Objectives

- a) To Inculcate a sense of social responsibility among the trainees and employees by aligning SBA
- b) To inspire citizens through faculty- student led sanitation programs.

#### Why and how it started?

Post Graduate Institute of Medical Education and Research (PGIMER) is a tertiary health care centre with about 8500 patients accompanied by attendants visiting the institute daily. Main source of waste generation in institute are OPDs, wards and OTs along with general waste from canteens and hostels. Besides this, the local voluntary organizations provide free food to the poor patients and their attendants outside the main gate called *Langar* that continue to generate additional waste. The area outside the main gate is neither taken care by the PGIMER nor the municipality of the city and is left unattended.

Driven by the PM's appeal and considering the sanitation status around the Institution, the research scholars of NRL started this venture on October  $2^{nd}$  2014. Every Friday, after working hours, the volunteers started devoting two hours in cleaning up the area inside and outside the institute campus.

### Plan of action

#### Inspiration

Following the speech of Prime Minister Mr. Narendra Modi motivating citizens to initiate SBA @ 2 hours every week, Prof AA initiated the program in campus and highlighted the importance of sanitation by role modelling of academics.

#### Vision/Mission

The mission was to convert PGIMER as a cleanest and the most beautiful campus in the entire world by active engagement of faculty and students.

#### Team coordination

One of the senior faculty members belongs to a family of retired paramilitary personnel where cleanliness and discipline is of paramount importance. This enabled him to disseminate the sanitation behaviour among students. This also catalysed development of a new social bond between students and faculty and mentorship between them has been established.

#### Roster preparation

An activity planner was decided among the volunteers in a weekly rotation to take the leadership of that week and pictures, collages and videos of *clean India campaign* which was uploaded after each week's activity. One more responsibility was to challenge other academicians for the clean India campaign. This instilled leadership qualities among the volunteers.

#### Standard Operating Procedure (SOP)

A SOP was generated based on the weekly activities as well as to initiate new volunteers who wanted to join this campaign.

#### Activities carried out by the volunteers

## *Picking up the scattered litter on roads and pavements*

Volunteers of NRL regularly gathered at a place, each week (different from other week), soon after their lab work and spent 2 hours cleaning the dirty areas around and picked up litter as they walked through a stretch of about 1 km. This has continued unabated for past 229 weeks @ 2hrs each week.

#### Interaction with general public

After the weekly cleaning activity, the volunteers assembled to interact with the waiting visitors and patient relatives to educate them about the importance of clean surrounding as most of the people among them lacked awareness about benefits of proper sanitation (figure 1). They were also taught about usefulness of maintaining hand hygiene by relating it with communicable diseases. The handouts containing vital information were also distributed among the people.



Fig. 1: (A) An artist capturing the event on canvas, surrounded by interested onlookers. (B) Workers installing large dustbins at the Langar area outside institute main gate (C) One of the volunteers addressing the gathering explaining the importance of the campaign (D) People watching the video clips and cartoons related to the campaign.

## Hand washing

The research team laid special focus on hand washing technique as it is important in preventing communicable diseases [12], as prescribed by World Health Organization (WHO) because most of the bystanders were poor, uneducated and uninformed individuals from different states. As infection spread through poor hand hygiene, proper hand hygiene has potential to save many diseases from spreading and is important technique for disease prevention. Volunteers demonstrated the hand washing technique (figure 2).



**Fig. 2: Different activities to inspire and educate the patients.** (A) Precaution while coughing and sneezing. (B) Standard Hand Rub procedure for hand hygiene. (C) A handout prepared by the volunteers to distribute among onlookers.

### Pledge

After all the instructions were given, most of the people and volunteers gathered together to secure a pledge from onlookers and participants in order to keep the surroundings clean, just like they would keep their houses clean. Following the pledge, an informal consent was obtained from the team regarding wilful participation in the initiative, without any peer pressure.

#### Updating weekly campaign in Swachh Bharat website

All the information regarding *SBA* was uploaded on the government website www.swachhbharat.mygov.in in a weekly manner so that the team's progress was visible to all and others could derive inspiration from it.

The recent uploaded pictures can be reviewed at https://swachhbharat.mygov.in/user/907433

#### Challenging others to join the campaign

Volunteers also challenged many academicians every week. They also inspired common people during their interactions to further challenge additional 7-9 individuals such that these individuals could challenge another group and so on. As this network grew, the awareness of the importance of Cleaner India spread rapidly. So far, the volunteers of NRL have challenged more than 1800 individuals. More than 15,000-20,000 individuals have been influenced so far through this campaign.

## Designing comics and article

Narratives related to sanitation were published in Annals of Neurosciences and other Pubmed resources, also profiled in the form of an educational comic, 'Magical Broom'. It was prepared for the children to highlight the importance of sanitation. This comic was distributed among kids, showcasing the real-life role modelling experience through look-alike characters. Magical Broom can be openly accessed at www.annalsofneurosciences.org. (figure 3)



Fig. 3: Comic "The Magical Broom", released by Neuroscience Research Lab to teach children's about Swachhta.

## Celebrations during Prime Minister Mr. Narendra Modi's visit

It was a coincidence when the Honourable PM, himself visited the Institute for 34<sup>th</sup> Convocation in 2015. The cleanliness drive heightened up to the new level when the local administration went on a plantation, converting the barren land into lush green lawns, painting the outer wall of the Institute overwhelming the previously stained marks of urination and *tobacco masala*. The team members were equally thrilled to witness the sudden change as the team vowed to sustain the "PM effect" in the adopted area around main gate.

### Results

## *Cleaner environment inside and outside the Institute*

After 4 years of continuous efforts, the visible changes brought about in the immediate environment of the Institute has attracted both media and Govt, whether in the form of awards or citations. The area outside PGIMER main gate, which was adopted by the team, has brought a tremendous transformation in the level of cleanliness and general orientation of visiting patients who continue to transmit the message among themselves. The street vendors show increased responsibility towards managing their wastes.

According to the Peter F Drucker, management is about doing the things right and leadership is doing the right things [13]. The volunteers with the help of local people have shifted the *Langar* area to the concrete pavement so it is cleaned easily after distribution of meals. This one policy has shown a broad transformation and has been very effective in regulating the generation of waste.

Managing the patient population is the most challenging job, due to their short and periodic presence in the Institute for treatment. Therefore, educating and inspiring them towards sustained cleanliness and improved sanitation appears to be short-lived because the patients change over time. However, due to continuous weekly effort by the team, there is increased awareness and in maintaining cleanliness in the area. It is pertinent to mention here that due to the effectiveness of the campaign the Institute administration also played an important role in changing the landscape of the area over time. (figure 4)



Fig. 4: Activities done in various weeks.

## Sensitizing the Administration

During the entire period of the campaign, an effort was also made to sensitize the PGIMER administration so that the increased state of cleanliness could be highlighted within the campus. Letters were written to the Director, Chief Security Officer, Municipal Commissioner and Sanitation Department of PGIMER appraising of the situation. This led to the installation of several dustbins in various pockets of PGIMER such as the Upper Cafeteria lawn, Auditorium lawn, Coffee Shop, Parking areas adjacent to Research Blocks. Sanitation staff was deputed to clean the glass windows of Research Blocks and at times their sanitation team also joined the SB campaign, accompanied by other students and faculty members. 'Rain Basera' (night shelters) were also erected by the administration in order to accommodate patient's relatives who would otherwise squat and urinate on the open ground and litter in the adjoining lawns.

As a result of the efforts, a mobile public toilet has been installed (figure 5). Additionally, the team offered to help the Dept. to manage their staff and their duties, their priorities, and most importantly their accountability to the work they were performing. Last but not the least, Ministry of Health and Family Welfare instituted the award which was bagged by PGI as the cleanest Hospital of India Awards: The Quality Council of India and the SKOCH awards were given to NRL in appreciation of the social outreach done by the team. On 15<sup>th</sup> October, 2017, the volunteers of NRL received "Ideas for Bharat Nirman" award under the category "Behavioral Change", at 3<sup>rd</sup> India International science Festival (IISF 2017).



Fig. 5: Showing the instillation of mobile toilet by the city administration.

### The Social outreach narrative

The second most important aspect of this campaign was to create awareness among common men visiting the Institute or among those working there. Increment changes in the sanitation behaviour of vendors, who were initially uncooperative with this team, could be seen integrating with the campaign, showing a sense of responsibility to protect the adopted area as their own. The experience of participating in the *SBA* was a unique experience to all the volunteers because they drew a lot of attention from the staff, friends and strangers alike whom they encountered on the streets. Every time the strangers captured the photos and videos of the team of volunteers and glorified their efforts with a promise to replicate the same in their villages and cities. The growing cleanliness in patient area catalyzed and motivated the volunteers further and they were encouraged to continue the *Abhiyaan*, widening its scope and impact.

#### Pilot evaluation shows promising outcome

It is usually difficult to sustain any changes imposed on people [14]. The results of an independent survey carried out by research group from Panjab University were shared with NRL volunteer's team of PGIMER. This included 91 subjects and showed that 42% were aware of Clean India Campaign even though there is a dynamic population of people from four states. Using theory of diffusion model [15, 16], we have illustrated (figure 6) the change that brought about by NRL volunteers in the society. The bell-shaped graph shows the population and the blue colour which represents the awareness created.

## Introducing Academic Social Responsibility (ASR)

On the line of Corporate Social Responsibility (CSR), [17, 18] the author team under the leadership of Prof. AA conceived the idea of Academic Social Responsibility (ASR).

CSR is a business model that ensures sustainable business development by delivering benefits such as economic, social and environmental to stake holders. Similar to CSR, the academicians (scholars/students) ought to have a social responsibility and give back to the society [19]. NRL volunteers showed that 'gloves' in the hands of students are meant not only for experiments and surgeries but also for picking up waste as a social responsibility. Thus, they tried to establish a concept of Academic Social Responsibility (ASR) for serving the society [20], and developing a better and beautiful India by creating role models among the academicians.

## Discussion

The activity of cleaning and collecting the garbage has often helped to sensitize the people about health and hygiene. Improved sanitation has pronounced effect on people's health and wealth. Sanitation is un-ignorable fact that not only saves lives but it is also associated with economic growth [21].

The NRL team set an example for their immediate locality by sustaining the program for more than 4 years, the longest social work ever taken up by any scientific community in the city. The volunteers continue to participate in the campaign creating awareness about Hand washing technique, coughing methods, educating the patients and bystanders about how infection originates and how it can be prevented by simple hand hygiene Interaction with people also bridged the chasm that exists between the scientists and the society. Spreading awareness among citizens requires sustained effort. This is even more challenging for a country with 1.25 billion people, majority of whom are uneducated and poor and live in unhygienic surroundings. This necessitates an effort which is



Shift of change from NRL volunteers to Public shown via Diffusion of Innovation Model

Fig. 6: Representing the response of SBA through theory of diffusion model.

locally addressed in all Institutions. Strict Laws and rules can add some impact to the cleanliness campaign because the enforcement of workmanship by street sanitation employees can ensure complete compliance to the job at hand. A study conducted among the residents of hygiene and sanitation practices in Thailand, Ethiopia and Kenya showed that continuous health education has failed in bringing the change in the practices of the households [22]. Unlike propagating only health education the volunteers themselves worked on the ground around the campus along with creating awareness of sanitation and hygiene which has made a stronger impact.

House wives and mothers are the primary teachers of the children and lead the practices of the entire house. A study conducted in the rural West Bengal has focused on the behaviors of the unsafe disposal of child faeces showed a prevalence of 72.4% [23]. An initiative like the one from the PGI showcasing a behavioral change that can be brought among mothers during their hospital stay which can bring change in the community. The change of bringing out the research scholars and the doctors from the closed environments or laboratories to the on-ground was quite effective. They were successful in instilling a civic responsibility among the public. This also decreased the superior and inferior concept between the educated and uneducated sectors of society which is quite prevalent in India.

A study from the villages of Uttar Pradesh and Madhya Pradesh shows that 76% are unaware of SBA and its implications [24]. PGI provides care to around 8500 people per day who comes from various regions of the India. Being a government institution and its cost-effective treatments, it accommodates mostly the rural population; awareness and inculcation of sanitation importance would be a little easier which makes it more sustainable because of its extensive outreach. This approach can also be replicated in schools. It is easy to train the teachers to emphasize cleanliness among school going kids. It could be incorporated as a practical activity with credits for kids.

According to Union budget, 2017 which states, 60% of sanitation coverage has been improved in the rural India [25]. To reach out to rest of the India, NRL volunteers would suggest taking the NRL volunteered PGI initiative as a working model for the sanitation awareness by the government and implementing in all the educational institutions (Medical or otherwise).

## Challenges during the Journey of Swachh Bharat Abhiyan

Many challenges were faced by the team of volunteers who led the Clean India activity spreading awareness. With the assistance of sanitation Department, the major areas of activity were identified where garbage was generated and remained unattended. The volunteer team started randomly cleaning the area around the institution and finally adopted the area outside PGIMER main gate (and vowed to transform that unhygienic entrance of PGIMER into a defecation free entrance). The activity became more and more organised with regular adherence to rosters. The campaign has been criticised by many academic intellectuals within the Institution suspecting the motive behind this but the response was spontaneous: "*Jab jago tabhi savera*" (it's never too late) confessing that the inspiration came from the honourable Prime Minister's Oct 2, 2014 speech.

## Conclusion

This program is unique, novel and rarely seen especially in institutional setting which is acting as catalyst for the promoting better health care delivery which can be seen by the improvement in roadsides, lawns, parking lots appear cleaner than before, the pot holes have been converted into green patches; the site of paper plates, thrown away by the patients, have been replaced by signboards. This gave a tremendous sense of achievement and immensely satisfying experience among the NRL volunteers.

Such an effort could be emulated by other Institutions in India and other African or Asian countries where similar conditions exist. The knowledge, expertise and management skills of the faculty have not been adequately exploited in this direction so far.

## **Conflict of interest**

The authors declare that there are no conflicts of interest.

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#### References

- 1. Correspondent H. India is home to world's largest poor population Hindustan Times Oct 05, 2015.
- Khan M. Growth star India overtakes China as world's fastest growing major economy The Telegraph 2016 [cited 2016].
- Reddy KS. India's aspirations for universal health coverage. New England Journal of Medicine. 2015;373(1):1–5.
- 4. Jayachandran. The great Indian sanitation crisis Livemint 2014.
- Lack of sanitation can be Zause and effect of poverty: India The Economics Times 2014.
- Ali E, Van Den Bergh R, D'hondt R, Kuma-Kuma D, De Weggheleire A, Baudot Y, et al. Localised transmission hotspots of a typhoid fever outbreak in the Democratic Republic of Congo. Pan African Medical Journal. 2017;28(1).
- 7. Water Sanitation and Health (WSH) World Health Organisation 2004.
- Majra J, Gur A. India needs a great sanitary awakening. Indian journal of occupational and environmental medicine. 2008;12(3):143.
- Joshua Chia Yeong Jia LTS. Keep Singapore Clean campaign Singapore infopedia.
- Manisha M. Swachh Bharat: A scheme or dream. Indian journal of occupational and environmental medicine. 2015;19(1):66.
- 11. Swachh bharat cess (sbc) frequently asked questions (FAQ) Customs CBoEa 2015.
- Celik LA, Pancoe DL. Healthy school environment: effectiveness of hand washing instruction in an elementary school setting. NASN School Nurse. 2012;27(4):194–6.
- Rämö H. Doing things right and doing the right things Time and timing in projects. International Journal of Project Management. 2002;20(7):569–74.

- Bouton ME. Why behavior change is difficult to sustain. Preventive medicine. 2014;68:29–36.
- Robertson TS. The process of innovation and the diffusion of innovation. Journal of marketing. 1967;31(1):14–9.
- Kaminski J. Diffusion of innovation theory. Canadian Journal of Nursing Informatics. 2011;6(2):1–6.
- Wood DJ. Corporate social performance revisited. Academy of management review. 1991;16(4):691–718.
- Sheehy B. Defining CSR: Problems and solutions. Journal of business ethics. 2015;131(3):625–48.
- Charles M. Giving Back to the Community: African American Inner City Teens and Civic Engagement. CIRCLE Working Paper 38. Center for Information and Research on Civic Learning and Engagement (CIR-CLE), University of Maryland. 2005.
- 20. Kawulich BB. Giving back to the community through leadership. Advancing women in Leadership. 2008;28:N\_A.
- 21. Wimalawansa SA, Wimalawansa SJ. Environmentally induced, occupational diseases with emphasis on chronic kidney disease of multifactorial

origin affecting tropical countries. Annals of occupational and environmental medicine. 2016;28(1):33.

- 22. Biran A, Schmidt WP, Zeleke L, Emukule H, Khay H, Parker J, et al. Hygiene and sanitation practices amongst residents of three long-term refugee camps in Thailand, Ethiopia and Kenya. Tropical medicine & international health. 2012;17(9):1133–41.
- Preeti P, Sahoo SK, Biswas D, Dasgupta A. Unsafe disposal of child faeces: a community-based study in a rural block in West Bengal, India. Journal of Preventive Medicine and Public Health. 2016; 49(5):323.
- Swain P, Pathela S. Status of sanitation and hygiene practices in the context of "Swachh Bharat Abhiyan" in two districts of India. International Journal Of Community Medicine And Public Health. 2016;3(11):3140-6.
- Hitesh Bhatia RB. India Open-Defecation Free: Opportunities and Challenges. International journal for innovative research in multidisciplinary field May, 2017;3(5):6.

# Indian PM's evidence based wellness approach inspires politico-scientific activism

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The Indian health knowledge generation programs and policies are dominated by studies initiated either by the scientists, Physicians or the funding agencies and often remain limited to labs. Recently, the Indian PM reset this methodological approach by himself prioritizing evidence based approach to wellness over the pharma driven health research. On the 2<sup>nd</sup> International Yoga Day, he publically role modelled for the Common Yoga Protocol developed by Ministry of AYUSH (Ayurveda, Yoga, Unani, Sidha and Homeopathy), along with 50,000 local Yoga enthusiasts. This was widely televised in the country. He also appealed to the health policy makers to study if Yoga based intervention can prevent the increasing cost and disease burden of Diabetes. The India Yoga Association (IYA) quickly took cue from this appeal and formulated a customized Diabetic Yoga Protocol (DYP) as population based intervention plan, promptly funded by the Ministry of AYUSH. The said protocol was evolved by the eminent Yoga scholars from various schools, for primary prevention of Diabetes. It included 1 hour of daily exercises which included specific postures, breathing and meditation techniques which could be beneficial for alleviating muscle resistance to insulin and prevention of stress. The acceptability and cost effectiveness of Yoga in Indian health scenario was the basis for IYA to swiftly recruit about 1200 Yoga practitioners, rechristened as Yoga Volunteers for Diabetes Management (YVDM). The national survey for prevalence of old and new Diabetics was completed by the trained YVDMs within a record time of 2 months, surpassing the earlier national effort which had taken 7 years. The entire lifestyle intervention project was executed within 10 months with alacrity and enthusiasm of YVDMs. About 2, 40,000 individuals across 64 Indian districts were screened through house to house visits in anticipation of the statistical sample of 24,000 Pre-diabetics and Diabetics. This was based on Indian Diabetes Risk Score (IDRS), conversion rate and incidence of disease. The resulting pre-diabetics were enrolled nationwide in the study and were physically monitored continuously for compliance to DYP for 3 months for any possible halt of conversion of Pre-diabetes into Diabetes. This was analyzed by blood sampling, stress and demographic questionnaire pre and post DYP intervention. The Yoga academics are upbeat at the prospect of publishing the outcome of intervention of Yoga protocol as well as awareness generated in the process. For this a randomization methodology consisting of two locations in each village and a city of a district were randomly selected, with each alternative location, separated by 6 kms, serving as waitlisted control for Yoga intervention. The execution of the project was aided by IT professionals who developed Apps for collection and collation of data from subjects who underwent 3 months of Yoga. The Senior Research Fellows who coordinated the YVDMs through free whatsapp, also evaluated stress before and after 3 months, and additionally, collected information about substance abuse, BMI and disenchantment with use of medicines. The trial was registered in the Clinical Trial Registry of India.

The stupendous success of the deployment of nongovernmental, non-medical human resources, their training and the intervention of the yoga module, in such a short time, bears testimony to political expediency and quality assurance in installing Integrative Medicine in India. Preliminary results have revealed the efficacy of the customized protocol in halting conversion of pre-Diabetics into Diabetics. Much like China, India needs to overcome the reluctance shown by successive Govts in integrating modern medicine with popular traditional approaches. The quality of methodology also promises brighter prospects for implementation of 'Ayushman Bharat', the flagship program of Govt of India aimed to provide record health insurance cover to about 500 million poor Indians. Despite growing resistance of Indian Medical Association to integrate traditional medicine with modern medicine, Govt appears unfazed not only in promoting wellness centers across the country but also in consolidating Yoga skills through popular accreditation system for quality Yoga intervention.

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## Development and implementation of ZED-YOG quality module: *Niyantrita Madhumeha Bharata skill* development initiatives

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#### **KEY WORDS**

YOG	
ZED	
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Quality	

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#### ABSTRACT

health awareness.

Background: Government initiatives and schemes for global healthcare improvement require efficient implementation which can transform the quality standards. We redefined the purview of Good Laboratory Practices (GLP) in the basic research investigations in order to create a benchmark of quality standards for conducting translational research.
Methods: We propose Zero effect-Zero defect Youth Oriented GLP (ZED-YOG) as a management tool for funding agencies to monitor data generated in labs funded by them.
Summary: This strategy can not only promote enhanced data scrutiny, validation but also

**Key message:** *YOG* will ensure the communication of audited research data generated from publically funded national agencies

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## Introduction

In the twenty-first century, the global healthcare management has been transformed through policy reforms and innovative technological interventions. A qualitative and quantitative assessment of clinical research and laboratory settings is crucial as their decisions influence the critical care of patients. Data fabrication, falsification of research data, authorship disputes are among the prime cause of research misconduct reported throughout the world, not only in biological sciences but also in other scientific disciplines [1]. Human errors have brought down million dollar Mars mission in the past as a result of failure in checks and regulations [2]. Similarly, recent stem cell research related incidents of misconduct have contributed to a change in society's opinion regarding science and its harmful effects. This necessitates applicability of quality module and quality assurance in order to ensure the credibility of processes, services, management, research and health care. Similarly, establishing the quality driven research facilities will ensure a competitive translational research among faculty driven research projects [3]. Various institutions have implemented or mandated one or other regulatory norms including Good Laboratory Practices (GLP), International Organization for Standardization (ISO), National Accreditation Board for Testing and Calibration (NABL), National Accreditation Board for Hospitals & Healthcare Providers (NABH) etc. for specific healthcare sectors. However, there are no mandatory policies for implementation of quality standards in the basic research as well as national public health initiatives for improved public health and research practices.

GLP was developed by Organisation for Economic Co-operation and Development (OECD) to regulate clinical trial and pharmaceutical studies but not the basic research. The Neuroscience Research Lab (NRL), PGIMER, Chandigarh, India transformed the quality management system to regulate the basic research laboratory based on requirements of day to day research conducts. Therefore, GLP was introduced in 2008 for creating a scaffold for quality management. GLP was later redefined by this group for implementation in the basic research investigations without diluting the core principles of GLP or research. It fulfilled the needs of research functioning as well as the needs of research personnel for their professional and personal development alike.

In the under-developed and developing countries, various government flagship initiatives have been launched but systems of data monitoring is lacking. There is also dearth of compliance to quality standards in the public funded government initiatives involving massive human research and epidemiological data. The major two national initiatives focusing global health were International Yoga day (Global wellness) and Niyantrita Madhumeha Bharat (Diabetes control movement). Another national initiative, Zero effect zero defect (ZED) was a recent implementation of Government of India which focuses on error free manufacturing capabilities with minimal environmental impact. ZED was proposed as the effective to change the dynamics of economy by focusing on manufacturing as an engine to sustained growth. We, therefore, sought to acquire processes involved in implementing ZED scheme with integration towards Quality driven skill development and empowerment of youth in the Government of India's (GOI) yoga-based intervention initiatives. We propose the term ZED-YOG (Zero effect zero defect -Youth Oriented GLP) which inspires propagation of the integration of youth driven implementation of quality standards in the management of these government programmes by mandatory integration of Yoga research activities in offices and healthcare organizations.

We discuss our effort to align the Government of India's initiatives with existing quality management research systems in order to provide an organized and successful outcome of the initiatives. Government of India has launched three significant initiatives which were implemented to transform the gamut of Health and manufacturing sectors in India. We mobilized and channelized the youth to complete two mega programs of GOI through ideologically similar ZED programme. This has been accomplished through existing GLP module of the NRL, importantly, by training more than 100 student in this maiden effort. These students were trained by the experienced lab personnel with expressed purpose of skill and leadership development. We emphasized the documentation of minimal error rate, penetrence of standardized yoga protocols in work place, periodic monitoring through digitization efforts defined as zero defect. In line with ZED effect in the "Make in INDIA" concept of manufacturing sector, the research sector could also be driven by ZED policy. Simultaneously, NRL's community outreach programme, encouraged by Government's Swachh Bharat Abhiyan (cleanliness drive) was also linked to the camps. Yoga camp activities were followed by Swachh Bharat activity at the camp site. We define this to be "Zero Effect" as the biomedical waste generated at camp sites is safely disposed according to the standard biomedical waste segregation protocol.

Prime Minister of India, Narendra Modi asked the world leaders to adopt an International Yoga Day, emphasising changing lifestyle as means to lead healthy life advocating policies for climate change. Addressing the 193-member UN General Assembly in United Nations, Prime Minister Modi said "Let us work towards adopting an International Yoga Day," Noting that Yoga is "an invaluable gift of our ancient tradition", he said: "It is not about exercise but to discover the sense of oneness with yourself, the world and the nature." "Yoga embodies unity of mind and body; thought and action; restraint and fulfilment; harmony between man and nature; a holistic approach to health and well being," he said, adding "By changing our lifestyle and creating consciousness, it can help us deal with climate change." During the 2<sup>nd</sup> International day of yoga (21st June 2016) held at Chandigarh, The Indian Prime Minister gave a clarion call to all Yoga institutions to focus this year, on taking up several programs to promote yoga for Diabetes. NRL took to the call and analysed the effects of Yoga protocol on biochemical, anthropometric and molecular changes in persons practising Yoga, and integrating it with ongoing research projects. Niyantrita Madhumeha Bharata

(NMB) is an ambitious national project for controlling Diabetes through yoga intervention. National Diabetes Control Program (NDCP) routed through Central Council of Research in Yoga and Naturopathy, New Delhi, and implemented by the Indian Yoga Association (IYA) (IYA is an association that has members from all major traditional yoga *paramparas* of the country). NRL took up the project and has analysed the results from the 3-month intervention on prediabetic and diabetics screened from house to house survey in North India.

This paper discusses the methodology adopted to carry out the NMB programme to enhance the credibility, back-traceability of the data obtained from a facility following GLP quality module. We integrated two different concepts ZED and YOG (Youth Oriented GLP) for seamless implementation of the abovesaid program.

## Methods

### Yoga protocol for NMB

Quality Council of India, in coordination with AYUSH, Government of India, developed yoga protocol for pan-India diabetes control. More than 9000 individuals were selected pan-India for participation based on the IDRS score. We focused on North Indian region (Chandigarh) for implementing NMB initiative.

## Orientation to Yoga Instructors

Orientation classes were provided to all Yoga volunteers for diabetes management (YVDMs) regarding the NMB program and different phases of entire regimen. Methods of administering the questionnaire were explained along with demonstration of measurements of anthropometric variables and precautions. Orientation class regarding hands on training of screening procedures with mock drill of screening session was carried out.

## YOG (Youth Oriented GLP) Module

Basic research investigations and procedures are dynamic in nature and need several rounds of modifications. Therefore, sustainability of the module was maintained by continuously improving this module through student-oriented protocols. One of our improvisations was to regulate and improve the functioning of basic research investigations through digital processes. We digitalised the procedures for GLP compliance, human resource skill development, environment safety, Intelligence, Emotional, Spiritual Quotient (IQ/EQ/SQ) of researchers, communication skill development, Security of research data and premises, economic viability and productivity which were helpful to formulate new policy changes for better regulations in this field.

## Methods of Identifications of the Problem

The responsibilities for all the activities such as policy making, administrative, documentation and testing etc. were distributed among the staff. The problems in all respects were identified by the concerned staff in that activity and document in the deviation sheet. It was ensured that the Study Director was kept informed and the concerned steps were taken to implememnt data capturing sheets called the Data Recording Sheets (DRS). There was a three tier Problem Identification System involved in the study, at each level of staff personnel:

Study Director

ANNAI S

- QA Personnel
- Technical Staff/ In-life observer

## Policy

Measures for corrective actions were formulated when nonconforming work or departures from policies and procedures in the management system or technical operations were identified. Responsibilities for the actions were centred around the in-life observer who was responsible for maintenance, calibration, breakdown reporting/documentation for individual instruments. For procedural/technical errors, the experimenter was responsible for reporting and documentation. The QA personnel reported this to the Management and any deviation or amendments in the protocols was finalized after thorough discussion between experimenter, QA personnel and the Management.

## Adherence of national initiatives to the Quality module in NRL as "Zero defect Policy"

## **Master Schedule**

Each research staff mandatorily proposed a weekly plan of the work to be completed in a month to plan the entire month. Master schedule was to be submitted to Quality Assurance (QA) cell before the beginning of the month. Master schedule of NMB camps were also prepared as per Figure 1. QA reviewed the progress of the research and technical staff at the end of the month through one to one interaction. Students prepared a draft in the Microsoft word document and mailed it to the Quality Assurance personnel to reduce the paper work. Master schedules were kept in a format by QA personnel in an electronic format.



#### Fig. 1: Master Schedule of date wise NMB Camps.

## Standard Operating Procedures (SOPs)

Experimental and administrative procedures performed in the laboratory adhered to the corresponding SOPs in order to streamline lab experiments and related procedures including purchase procedures, cleanliness drive, publication of Annals of Neurosciences (PubMed indexed Journal published from the lab), project writing, grant writing, thesis writing etc.

Using similar quality modules, SOPs were developed to streamline entire NMB yoga camps as explained in Figure 2.

## Standard Operating Protocol (SOP)

### NMB Camps

Neuroscience Research Lab, PGIMER, Chandigarh-India

*Niyantrit Madhumeha Bharat* (NMB) is the Yoga initiative from AYUSH and SVYASA for controlling diabetes in India via Yoga. Under NMB, blood testing camp to check diabetes were carried out across India. This protocol represents the structure of management to handle the blood testing camps.

The whole camp activities were divided into following activities which was done in serial order:

- Token Distribution: Token number is distributed to people coming to manage crowd and chaos.
- Master Coding: Each person is assigned with a unique master code which is exclusive for him only and this code is written on all the forms and vials in which blood is collected.
- Registration Form: Registration form filled for each person by indicating master code on top of the form.
- SRL Form: SRL form is filled for each person by indicating master code on top of the form.
- Height/Weight/Waist Circumference/Hip Circumference: measurements are taken by using weighing machine and measuring tapes. After that write that on form.
- 6. Blood Pressure: measure and write on form.
- 7. Blood Sampling: Blood sample taken by SRL team.
- Glucose Drink: Glucose is given to prediabetic person only. Diabetic person should take regular food
- 9. Form Filling: Detailed Neuropsychology form is filled after person give the blood sample
- Photography/Crowed Management/Swachh Bharat: These activities are keep running with other activities during camp.

Fig. 2: Standard Operating Protocol of NMB camp.

## Data Recording sheet (DRS)

To minimize the procedural errors, DRS were formulated along with SOPs for the real time monitoring. This was prepared in consultation with Study director and consisted of the columns for identification of SOP, along-with control of the document through Quality Assurance (QA) cell. DRS was issued only at the time of conducting the experiment and re-submitted to the QA after attestation from the Study Director. Data recording sheets were followed in all procedures of NMB data analysis.

## Quality Assurance Review

Independent review of infrastructure and facility-based QA audit was carried out once in a month. Study based QA

review encompassed the review of the work planned by the research scholars as per their master schedule. Deviations from the master schedule were documented and carried forward for the next month. Independent verification of experiments was carried out to check the compliance to SOP. QA review sheets were prepared in the Microsoft word document.

## Log Sheet and Log Books

The log sheets and log books maintained for the entire chemical, refrigerated reagents and all sophisticated instruments are used for documenting usage. These are useful for troubleshooting not only the technical problems but also in ensuing timely re-ordering reagents.

## **Checklist Based Management**

Checklists were developed to ensure the completeness of the task assigned to students which compensate for the human limitations. Checklists were formulated for all the academic or administrative lab procedures including, synopsis preparation and its approval through Dean Doctoral Committee (DDC), presentation of the progress of research through Doctoral Committee (DC), PhD viva, grant writing, seminar presentation, human and animal ethical clearance, visa application for travelling for conferences, manuscript writing etc. Checklists were stored in the common domain of the lab networking system. Thus, it could be used among the closed user group for guidance without having the need to approach a senior/Study Director. This created a system dependent guidance system for the trainees for implementation with respect to NMB project execution.

## VPN based servers for digital data accessibility and storage

Server based virtual private network (VPN) in the secured network is installed in the Neuroscience Research Lab for the storage, security and remote accessibility of research data. Usually, in industries or IT sectors the server-based access and storage are available; however, introducing it to basic research facility in a Medical Institute is challenging. The server spaces were utilized to import the data obtained from NMB camps. Server domain was allocated to each student and staff to store the confidential research data. Only study director was authorised to access all domains. Besides having personal drive, every computer was allocated with official user domain among closed user group where research data is fed in the form of SOP, DRS and master schedule. This domain represented a personal and common drive in which research data could be accessed in a secure fashion by the study director in order to restrict the access of intellectual property and common administrative procedures, respectively. Network security system, through firewall, was created as a barrier across internal network. Another network was geared up to provide security of confidential research data that protects the server against various threats from public networks. Remote access through virtual private network provided secured access to data from anywhere through internet and ensured safety of lab assets by real time surveillance.

## Real Time Monitoring (CCTV)

NRL was kept under the surveillance of CCTV camera and real time monitoring was enabled through VPN system. It acted as a deterrent for any unforeseen security lapse thus it also provided a secure environment to the female members of the lab and monitoring of the research activity in lab.

## Master Coding of Individuals And Samples

Participants were provided a unique code according to the ongoing GLP led quality management system of NRL. This maintained confidentiality of participants, data blinding and management of the crowd. Samples obtained were coded for blinding and kept according to the existing quality standards. Data was digitised through new team under the supervision of experienced personnel.

### Personal Discussion and Lab Meeting

A day was allocated to every student for personal discussions regarding the research problems, progress and purchases with the study director. Every experimental and purchase procedure was structured into indent, benchmark checking, and assessment of log sheets maintained to see the previous purchase.

#### Administrative documents

(Log books, Log sheets, Inventory sheets, temperature sheets)

#### Inventory Sheets and Master inventory

Lab reagents, Kits and glassware were kept in various shelves and refrigerators. These inventories and their management were distributed among students who looked after the exchange of material. Inventories were submitted monthly to QA, who prepared a master inventory. Master inventory was used to check the location and available stock of any chemical or kits. Quarterly, the hardcopy of the inventory sheets was updated with freshly updated quantity of the stock. To reduce the paper burden on this task, the quarterly review of inventory was carried out and electronic records of the inventories were sent by the students to the QA and Master inventory was maintained by the QA personnel.

## **Zero Effect Supporting Initiatives**

#### Bio Medical Waste Management

Rigorous biomedical waste management training was provided to the students with periodic orientations to the trainees. Biomedical waste was segregated in four different polybags. Black containers were used for general waste, Yellow containers for soiled infected waste, Blue containers involved sharps and red containers included plastic wastes.

## Printer/Paper Usage

Printers were linked to each computer/Laptop in the NRL. Printer log was monitored for each research personnel in order to save resources.

## Swachha Bharat Abhiyaan (Clean India Mission)

Zero effect programme was also encouraged by Swachha Bharat Abhiyaan (SB) led by Neuroscience Research Lab. Volunteers from the NRL devoted two hours each week for continuation of cleanliness drive continuously for 203 weeks till date. The activities were also submitted to government portal Mygov.in and propagated through Facebook and WhatsApp groups. Government officials from scientific, academic and social backgrounds were mailed and challenged to propagate the cleanliness drive further in an ice bucket challenge mode.

### Educational Programmes

Scientific symposiums were carried out to disseminate the importance and challenges in implementing quality standards. Research projects and thesis works were connected to quality assurance programme in order to orient the researchers about implementation of quality standards. These trained researchers further oriented the yoga teachers and volunteers of NMB national initiative for integration of quality parameters in the execution of NMB. Researchers were oriented to adopt the quality parameters from experts in the field.

## Validation of NMB Data

Entire set of NMB documents and data were validated by trained personnel. Each participant was telephonically identified, excel files were cross checked for manual errors in digital entries and the statistical data was also validated by an independent investigator.

## **Results**

In 2014, Quality Council of India (QCI), recognized NRL for D. L. Shah National award for "Redefining Quality standards in basic research investigations by broadening the purview of Good Laboratory Practices (GLP)" under research category. In 2016, Quality council of India again recognized this effort and awarded the NRL for "Digital Research Lab for Enhancing Capability: Towards Skill Development and Community Outreach". For the first time, this award was constituted to create a special category to accommodate the unique initiative.

## Financial and tangible benefits of the quality module

The research chemicals upto the scale of microlitres were laboriously documented for as per daily use. Purchasing time was streamlined through availability of chemicals and correspondingly documented in the log sheets. Experiment wise documentations ensured auditability of experiments. Digital scrutiny encouraged improvements in the purchase and accounting procedures. Intra and Inter laboratory auditing of various grants were carried out to ensure auditability.

### Storage and Security of the research Data

Large data saving capacity makes this server unique in the basic research settings. Server automatically updates the storage capacity after one year. Thus, the data can be extracted from the server within this time-frame. Server is also used as a data backup device. The security of crucial research data, which is a requirement in the basic research settings, is stored under the control of firewall which disables any possible hackers efficiently. Network layout plan is described in figure 3.



Fig. 3: VPN based Network layout plan.

The Server based networking system encourages controlled utilization of papers as it keeps the log of printer usage for each personnel. In this way the system is kept environment friendly as it is important in the smooth functioning and saves time. NRL became the first entity to finish 100 hours of SB in India. It trained youth to participate in the "Swachha Bharat Activities" through the camps NMB and International Yoga Day. After each of such camps, the completion youth driven *Swachhata Abhiyaan* were carried out for orientation of staff towards ZED-YOG.

### NRL Social networking

NRL team enhanced its efficiency through WhatsApp group chats. Professional guidance's, suggestions, sharing ideas and instructions were facilitated through the WhatsApp group. It reduced the communication gap between the study director and other research staff. NRL's activities, achievements, future programmes are projected through a separate Facebook page. Implementation of quality module has increased the credibility of data published through the scientific fraternity. Benefits of such quality module in various research areas is depicted in Figure 4.



Fig. 4: Benefits of ZED-YOG quality module.

## Discussion

The student/youth driven GLP module enhanced the reproducibility of data and error reporting of research data and internalised the quality system in research practices, thereby facilitating a higher sincerity of purpose for research in Medical Institutes in India (paper in communication). It also sought to bridge the credibility chasm that exists between data generated from India and that from the West, because of which the best research from India is rarely published in top Journals. The implementation of this module has led to enhanced visibility in the research. Research papers written from NRL provide sufficient data which shows that this quality module has improved the quality of data generated [4–6].

The redefined GLP system encourages goal driven, self proposed monthly master schedule map of activities in

coordination with the study director, using the combination of SOPs, DRSs and master schedule applicable for various research projects. The Quality Assurance (QA) unit in NRL conducts periodical audit of the progress, compliance and reproducibility of experiments. The data generated filed in a defined format using a mandatory raw book, master code, calibrated instruments (with IO, OO, PO), log sheets with continuously regulated infrastructure and room environment provides the necessary back up for data retrieval. The data and samples which are archived in defined shelves or freezers, as the case may be, can be seamlessly used for future experiments saving precious resources. The current system is rare in any research settings specifically in the medical institutions. In view of the increasing government participation for global health programs, the implementation, backed by quality standards, is necessary. Ideological integration of governments quality module, ZED and our youth oriented GLP (YOG), provides a robust organizational system for success of science policy implementations in govt funded research labs. Manufacturing & Design capabilities, Quality/Environment/Safety assurance systems, People development and engagement systems, Standardization and measurement systems for quality and environment, Learning and improvement systems, Legal compliances are the key features of ZED which are being integrated with the GLP core principles.

SOPs facilitate the robustness of the system and enhances productivity of students and staffs thus reducing the scope of errors. It also results in internalising the quality principles in the youth. More than 100 volunteers working in various streams have been trained to work in a ZED-YOG fashion by adapting the NRL module of GLP and minimizing medical waste through Swachha Bharat Activity. The scientific analysis of the samples obtained from International Yoga Day (IYD) and Niyantrita Madhumeha Bharata Abhiyaan (NMB) camps were similarly evaluateds according to the existing quality management system developed by NRL. Successful implementation of government programmes such as IYD and NMB camps generated crucial authenticated data backed by Quality standards thus, necessitating implementation of quality standards in all government programs.

### Conclusion

Modified GLP module has been found to be effective to safeguard the accountability, back traceability of the research data and management of human resources. NRL strives to create a module which can be emulate by other basic research facilities in India. New policies can be formulated for the basic research settings using the quality module. ZED-YOG has capacity to develop a new generation of basic scientists striving towards quality-oriented environment with effective research output. The national initiatives with focus on global health research standards can consider adopting the ZED-YOG protocol in their work places.

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Authors don't have any conflicts to declare

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## References

- 1. Maurer JJ: The proper conduct of research. Avian Dis. 2007;51(1):1–7.
- Krapp M: Quality assurance in research and development: an insoluble dilemma? Fresenius J Anal Chem. 2001;371(6):704–13.

- Adamo JE, Bauer G, Berro M, Burnett BK, Hartman KA, Masiello LM, et al. A roadmap for academic health centers to establish good laboratory practice-compliant infrastructure. Acad Med. 2012;87(3): 279–84.
- Sharma NK, Sharma K, Singh R, Sharma SK, Anand A: CCL2 single nucleotide polymorphism of rs1024611 implicates prominence of inflammatory cascade by univariate modeling in Indian AMD. PLoS One. 2018;13(4):e0193423.
- Jindal N, Banik A, Prabhakar S, Vaiphie K, Anand A: Alteration of Neurotrophic Factors After Transplantation of Bone Marrow Derived Lin-ve Stem Cell in NMDA-Induced Mouse Model of Retinal Degeneration. J Cell Biochem. 2017;118(7):1699–711.
- Anand A, Sharma NK, Singh R, Gupta A, Prabhakar S, Jindal N, et al. Does DcR1 (TNF-related apoptosis-inducing-ligand Receptor 3) have any role in human AMD pathogenesis? Sci Rep. 2014;4:4114.

## Editorial

Annals of Neurosciences

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## Mapping and Characterization of Integrated Health Care Policy in India: A Recipe of Ministry of Health and Family Welfare

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The global crisis in health care is deepening. For the mainstream community, inexpensive quality health care looks like an illusion for a developing country like India despite having rich medical traditions and ancient healthy lifestyle. Healthcare systems need to understand the complex interplay of tradition, biology, behavior, socioeconomic, and environmental factors that shape health. These factors cannot be considered in isolation from each other. Planning effective treatment of disease requires addressing them all together, fully and integratively [1]. The Indian government has recognized 8 systems of healthcare viz., Allopathy, Ayurveda, Siddha, Swa-rigpa, Unani, Naturopathy, Homeopathy, and Yoga. Most of the hospital care in India are, however, based on the Allopathy and other system are mostly neglected [2]. Recent drug discoveries from the plants of Indian origin have opened new doors in healthcare [3], however, Yoga remains uncharacterized scientifically and therefore disjointed from premier Medical Institutes as treatment modality [4]. It is argued by many that Yoga could be integrated with the Allopathy especially for diseases that have no cure or are non-communicable. The investigators could therefore aim to design a policy which assesses the impact of integration of Allopathy, Ayurveda, and Yoga in health care systems in a scientific and evidence based manner. A module can be used for scoring of available Heath Care system and their impact in India. This may include number of patients visiting Allopathic Hospitals, Ayurvedic Institutes and Yoga Centers including the number of patients who have obtained the benefits from alternative therapies instituted in the premier medical Institutes. Quantification of work and stress profiles of allopathic, ayurvedic and yoga practioners can also provide important inputs for configuring these healthcare workers in mainstream hospitals regulated by the Government. Designing of integrative medicine-oriented policy based on such a pilot study is required so that hospitals, Ayurvedic Institutes, and Yoga Centers can work together in an integrative manner. Such a system will greatly help in making a better health care policy for current health care system and enable ranking of the hospitals in a systematic and evidence based manner.

#### **Disclosure Statement**

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### References

- 1 Patwardhan B: Ayurveda and integrative medicine: riding a tiger. J Ayurveda Integr Med 2010;1:13–15.
- 2 Shankar D: Health sector reforms for 21(st) century healthcare. J Ayurveda Integr Med 2015;6:4–9.
- 3 Sofowora A, Ogunbodede E, Onayade A: The role and place of medicinal plants in the

strategies for disease prevention. Afr J Tradit Complement Altern Med 2013;10:210– 229.

4 Qu S, Olafsrud SM, Meza-Zepeda LA, Saatcioglu F: Rapid gene expression changes in peripheral blood lymphocytes upon practice of a comprehensive yoga program. PLoS One 2013;8:e61910.

## Commentary

Annals of Neurosciences

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## National Medical Commission Set to Replace Medical Council of India after Gorakhpur Episode: A Case for Quality Assurance

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Non-medicos (scientists) joining the national medical commission (NMC) is likely to facilitate scientific advancement in medical practice in India by propelling indigenous research. This is likely to result in affordable tests and therapies, as doctors in India are unfortunately not trained for research unlike those in West (as curriculum of MBBS, MD/MCh, DM, etc., does not include basic research syllabus). This bill was likely to be tabled in Monsoon session on Indian Parliament but this case for quality assurance appears to have been delayed. This will impact expansion of genetic testing services nationwide whose revenue would have been re-invested in training of medical graduates and generation of genetic database for cure of genetic disorders. The adoption of NMC will accelerate translational research and improve the provision for integrated health care which may provide solutions of incurable disorders as well as innovative means to address Gorapkhpur like episodes. Further, inclusion of Ayurveda, Yoga, and other alternative medical approaches in health care delivery will reduce patient rush and generate comparative data between modern medicine and alternative medicine, thus paving the way for regulation of costs of healthcare and save the precious lives.

Engagement of individuals from quality assurance in NMC is likely to ensure patient feedback and check out-

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E-Mail karger@karger.com www.karger.com/aon sourcing of investigations/tests through installation of treatment, testing, and patient cost audit protocols something, which could have been easily prevented in Gorakhpur episode in which more than 36 children died. This will ensure continuous monitoring of patient services through clinical audit, thereby improving the quality of patient service.

Patient cost audit will further ensure reducing "out of patient" expenses of patients as health economists have also been included in NMC which can evaluate the effect of private practice. This can additionally be achieved through audit of company sponsored conferences generated from unnecessary investigations/branded prescriptions that are suspected to be ploughed into conferences kitties for fun and frolic.

One example (of role of non-medicos in NMC) is to install IT tool enabled provision for surgicals, in house tests through the institute inventory management system, as also developed by Dr. Wakhlu of King George's Medical University (who won the SKOCH platinum award for his innovation and implementation of IT tools) thus saving costs of treatment for patients and empowering rural healthcare such as in Goraphpur. The resources saved can be earmarked for rural healthcare development and prevention of spread of infectious brain diseases.

Prof. Akshay Anand Editor in Chief, Annals of Neurosciences Neuroscience Research Lab, Department of Neurology, PGIMER Chandigarh (India) E-Mail akshay2anand@gmail.com With the help of inclusion of patient advocacy groups in NMC, it will establish the quality process so that (by engagement of patients engagement in NMC) rapid changes in practice of medicine benefits the patients, not doctors or scientists.

NMC must also include Yoga and alternative medical practitioners in ensuring its seamless integration and patient cost reduction in health budget. This can compensate for weak rural healthcare system for villages. It is only possible by integration of the role of non-medicos (patient advocacy, quality assurance, health economists, and scientists) in reallocating over staffed medical institutes to rural postings in rotation. The importance of generation of evidence from comparison of treatment outcomes between modern medicine and traditional medicine can be generated through integral healthcare, which was impossible with medical members of MCI.

#### **Disclosure Statement**

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## Commentary

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## Policy Research for Assessment of Quality Assurance Practices in Skill Development of Doctoral Programs in Medical Institutes

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#### Introduction

Doctoral programs in India are focused around empirical laboratory and field studies with theoretical and computational explorations aimed at addressing fundamental issues in the field of science. PhD students are often motivated to pursue the PhD by scientific curiosity, the desire to contribute to the academic and social community, and/or personal development. However, in the absence of basic research administration and because of overemphasis on patient treatment, the quality research of ecosystem in medical institutes remains soft [1].

DST recently started the Policy Research Fellowships to promote policy-related investigations. Since Science and Technology is now recognized as playing a significant role in advancing human, social, and economic development and addressing the aspirations of citizens across the world, the need to integrate quality assurance tools in Doctoral programs cannot be over-emphasized. An analysis of the nature of biomedical research in India indicates that most of the research has primarily been of academic nature and has rarely assessed the methods in research with any policy implications [2]. Along with "fabrication" and "falsification," plagiarism is one of the "big 3" crimes of the research fraud rising

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E-Mail karger@karger.com www.karger.com/aon in India [3]. Therefore, a need for quality control is urgent. A quality policy is required in Institutes for Doctoral Programs. This can be done by incorporating methods to render raw data verifiable, back-traceable, and auditable.

Introduction of a policy management system for doctoral programs in medical institutions can help in linking research with quality assurance so that the resources, time, and efforts can be utilized in an efficient way for enhanced productivity, innovation, translation, and skill development. Such assessment tools can enable the establishment of a quality system. This can ensure and validate the uniformity, consistency, reliability, reproducibility, and quality in research data. It is possible to analyze this by 4-tier assessment: (i) by way of measuring the time spent by students in PhD program, including regular laboratory hours, (ii) what are the quality tools used/created by them, (iii) their number of publications, patents published during the course, and (iv) whether any quality statements were inserted in their respective research publications. The student's skill development program can also be gauged by the number of their visits to national and international workshops and conferences as well as their participation in social outreach activities. The costs involved in completing PhD degree can also be documented.

Akshay Anand Neuroscience Research Laboratory Department of Neurology PGIMER, Chandigarh 160012 (India) E-Mail akshay2anand@gmail.com Such analysis can also include the number of principal investigators in the department and their qualifications, ongoing projects and those completed, amount of funding and the number of invited talks to national and international conferences, including ones on quality and management meetings. Their awards, grants, and leadership roles in the launch of social outreach programs for training of PhD students must also be measured. It is also possible to map the number of national and international collaborators, with interdisciplinary teams, if any, and the time spent by faculty with students on bench must also be assessed.

Similar quality audit at the administrative level can be done by assessment of administrative record keeping, file tracking, monitoring and documentation processes engaged by the administrative staff including efforts to continue providing guidelines, institutional independence to faculty, students and managerial support for procurement, and quality programs with allocation of various portfolios to various Deans etc.

The quality assessment must not exclude the funding agencies' commitment to implement quality audit of experimental facilities funded by them. Even the publishers or societies can make a commitment to periodically assess the journals, wherein all data regarding number of manuscripts submitted for publication, efforts to recall raw data from authors could be open to public eye. The retraction policies for articles must be matched to number of retractions executed by them. The policy research studies will help in improving the quality of doctoral programs in medical institutes and help in establishing individual quality assurance cells in research laboratories matched to the qualifications of PIs. Such studies will also help in ranking and mapping the labs in a systematic and evidence-based manner so that crucial national projects may be funded to facilitate "Make in India" program a grand success. If successful, it will help in improving research quality, social values, productivity, and skill development of PhD students across the country and world.

The policy scoring may also help in incubating ideas which may result in new tests and therapies, which are invariably imported at the cost of indigenous discoveries which are devoid of quality and benchmarking. Currently, the quality benchmarks are not mandated by funding agencies even though Universities have Quality Assurance Cells.

Recently, DST started policy research fellowships to promote policy research. Ironically, all post-doctoral fellowships were assigned to 5 centers of policy research. Interestingly, junior research fellowships were not provided to anyone which is a self-defeating step.

The periodic rolling out of policy research fellowships will help emphasize the importance of the need for linking release of research grants and fellowships in order to promote Science and Technology in Medical Institutes and universities.

#### References

- Lakhotia SC, Anand A: Excellence in medical research – can we make it in India? Ann Neurosci 2015;22:55–57.
- 2 Khaparde MS: Educational research in India: policy and practice. Educational Res Policy Practice 2002;1:23–33.
- 3 Juyal D, Thawani V, Thaledi S: Rise of academic plagiarism in India: reasons, solutions and resolution. Lung India 2015;32:542–543.

## Editorial

Annals of Neurosciences

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## Incubating Integrative Medicine in India through PMO's Atal Incubator Scheme of Niti Aayog

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#### Keywords

Incubator · Integrative medicine · Yoga · Niti aayog

#### Abstract

**Background:** Incubation centers are considered important tools to advance in a field of activity with multidisciplinary approach. The idea of incubation emerged long time back but it is actively pursued by funding agencies as a medium to propel community development. India's fast developing economy had limited tryst with Integrative Medicine until Indian Prime Minister, Narendra Modi, role modelled for Yoga in Chandigarh on the occasion of International Yoga Day. Integrative Medicine is a growing field and widely accepted as a cost-effective problem solving method that simplifies the management of incurable and complex disorders where modern medicine has little to offer. Summary: Development of integrative medicine health incubator is the key to development of multidisciplinary program that offers to reduce the cost of healthcare, out of pocket expenses and emphasizes on preventive healthcare as means to achieve a healthy population in a developing country like India. Key *Message:* Incubation center may become practical solution for many health problems in singular platform for healthier society by integrating traditional and modern medicine.

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#### Introduction

Integrative medicine is the emerging platform as it involves cure-oriented treatment including every aspect of a person such as life style, etc. Bringing integrated medicine into practice is a great challenge. Incubation centers can become one of the practical solutions for this. It will bring everything at a single platform. The idea of incubation centers emerged in the USA and from where it evolved in the atmosphere with the number of models varying from public to private incubation hubs [1]. Incubation centers are designed to promote economic growth, making best use of resources, survival and advancement of new start-up firms gradually, creating jobs and wealth opportunities, enhancing entrepreneurial environment, bringing up new technologies, escalating growth in a local industry. Initially, incubation programs focused on technology and services firms but later it extended and involved various other industries yet it remains unexplored in the medical institutes through which the potential to stretch the limits of health sector become a reality. The novel idea involves the integration of health care with modern and traditional medicine, which helps the patients with curable and incurable disease through a more scientific approach that does not necessarily depend on pharma investments (Figure 1). For example, a rehabilita-

Akshay Anand Neuroscience Research Lab Department of Neurology PGIMER, Chandigarh E-Mail akshay2anand@gmail.com tion center for persons suffering from lethal disease like Duchenne Muscular Dystrophy (DMD), for which cure is still far away, can provide awareness and relief by genetic counselling and rehabilitation that a Government Medical Institute is not geared up for. An incubation center for similar diseases is an urgent requirement, given the emphasis the current governments are laying on disability.

#### **International Status**

The origin of business incubator originated in the USA in 1959; then, it evolved further in Canada's economic development. There are many incubation centers worldwide. According to a report in 2006, there were 7,000 incubators around the world in total. A total of 1,400 were in North America, 1,000 in Europe, 200 in the UK, 400 in China, and 355 in Korea. India also had 120 incubators together with 40 Science and Technology Entrepreneurs Parks (STEP) [2]. United Kingdom Business Incubation estimated the impact of this incubation scheme on the country's economy and human resources, which proved that this could provide around 167 jobs per incubator, and root for approximately 30 entrepreneurial companies at a time. Although incubation centers for medical institutes are grossly lacking worldwide, there is increasing demand to cater to such a facility under a singular platform.

### **National Status**

In the Indian scenario, around 1980, National Science and Technology Entrepreneurship Development Board initiated the STEP and, in the early 2000, technology business incubators. India has nearly 120 incubators. There are major examples of incubation centers established in India such as SIDBI Innovation and Incubation Centre started by Indian Institute of Technology (IIT) Kanpur; Centre for Innovation, Incubation and Entrepreneurship, Ahmedabad; Technology Business Incubator, National Institute of Technology Calicut; Vellore Institute of Technology-Technology Business Incubator; and Amity Innovation Incubator; etc. [3]. The IIT-Patna developed a venture for medical technology on campus. In the scheme, they planned to work economically fit versions of machines like X-ray, MRI, etc., but the idea of bringing everything together at one platform is still lacking. The idea is to bring a patient-centered scheme that would focus on the establishment of AIC in underserved and un-



**Fig. 1.** Schematic representation showing integration of modern and ancient medical system of treatment and investigation.

served areas of preventive and curative healthcare delivery system for patients with curable and incurables diseases.

In this futuristic scheme, the idea is to incubate the start-ups for mentoring in the field of genetic testing of incurable Muscular Dystrophy, Physiotherapy and Yoga Outreach, Engineering necessary equipment for MD group and Nationwide Awareness program. Moreover, the nature of the scheme is financial and social inclusion of the MD Patient by connecting them to the mainstream, scientifically awarded community for better understanding of their rights and obtaining holistic care. The center also focused on providing holistic healthcare and management to the patient group of all sections of the society.

To provide effective healthcare to India's rural population is the basic aim of the mission, focusing 18 states which include Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Himachal Pradesh, Jharkhand, Jammu and Kashmir, Manipur, Mizoram, Meghalaya, Madhya Pradesh, Nagaland, Orissa, Rajasthan, Sikkim, Tripura, Uttaranchal, and Uttar Pradesh. Key collaboration in the international scientific community, NGOs, and engineering sector is essential for early implementation of these types of missions and to make these missions cost-effective for the poor. Different schemes have been introduced by the Government of India to devise strategies to enhance access to underprivileged people. National Health Insurance scheme is one among all schemes which provides health insurance to people from Below Poverty Line with the objective to bear the expenditure of health stocks; however, this has not been completely implemented in India.

#### Results

The proposed center can incubate preventive approach to spread of incurable disease in families, thus reducing both health budgets as well as empower the carrier females. The results of the study can give an insight into the burden of the problem of sporadic DMD/BMD cases. This can also be used to design health education and awareness campaign for primordial prevention of children born with DMD. Using the genetic testing facility on the global platform, it can be a source of policy initiatives to transform Indian healthcare sector by benchmarking Indian healthcare service which comprises traditional and modern medicine at cheaper rates. Due to the incurable nature of disease, another focus of the center is to provide not only genetic but also holistic approach for the MD patient in which the main focus could be on complementary and alternative approach, which includes Ayurveda, which is known to improve the health of incurable MD patients. Treatment with the yoga and physiotherapy could also be provided which may improve their health at greater level. As MD patients frequently face cardiovascular, respiratory problems and problems like muscle stiffness which can easily be reduced through Yoga-asana, Pranayama, and Physiotherapy, and these can be published in the international peerreviewed journals projecting traditional medicine in world literature.

Hydrotherapy can be other option for the patient in integrative healthcare that involves the use of water for pain relief and treatment will also be made available. Through this approach, not only health and mind but also their cognitive ability will be tested to improvement.

Neuropsychological rehabilitation can be another thoughtful idea through which cognitive domains can be analyzed through neuropsychology tests. These facilities do not exist anywhere in the country for the people who can hardly perform their day-to-day activity themselves and are an important part of our society. The main purpose of the proposed center will be to integrate the complementary and alternative holistic approaches including Ayurveda and Yoga.

#### References

- 1 National Science and Technology Entrepreneurship Development Board, Department of Science and Technology, Government of India. Conceptual Document on Technology Business Incubators – Developing Eco System for Knowledge to Wealth Creation. Technology Business Incubator, COMCUBATOR, MICA EDC, pp 1–72.
- 2 Kamdar M: Role of Business Incubation Centres in Promoting Entrepreneurship [Thesis]. Institute of Management Studies and Research, 2012, p 9.
- 3 Roshan Kumar: IIT Push for Medical Technology Start-Ups. The Telegraph, 2016.

## Editorial

Annals of Neurosciences

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## Demonetized Cost of Neuroscience: Time for "Modi" Brain Fund

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The Indian Prime Minister's audacious step to end dirty money and ban high-value currency notes in India is being widely argued as a big blow to terrorism, drug mafia and patient referral mini-economy that thrived on cash and counterfeit notes, and out-of-pocket expenses of patients. This has led to the channelizing of black money into the bank accounts of poor, providing a golden opportunity to launch new research projects related to affective neuroscience and examine its impact on the happiness index among poor. Social neuroscientists have an opportunity to study how the entire Indian society suddenly stands divided, not on the basis of cast, religion or language but as hoarders of black money and the honest tax payers, the rich and the poor, and Pro-PM and anti-PM media and its impact on social brain which has become a subject of intense debate among neuropsychologists. The recently held 3 state municipal corporation elections have proved the claims of media wrong that the long queues of individuals waiting to obtain cash from ATMs felt harassed. Not long ago, editorials that once endorsed "intolerance" in India, citing the drama of pseudo-intellectuals, to give up their awards, have stopped writing or finding holes in the new found joy of the poor who patiently waited in long queues for cash withdrawal, anxiously awaiting reforms about benami property and hoarding of gold.

The call for analysis of health benefits of PM's International Yoga Day role modeling, had barely stirred up the establishment of centers of integrative medicine in the country, that the "subjects" affected by demonetization

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E-Mail karger@karger.com www.karger.com/aon are getting ready to be recruited for neuropsychological analysis in such centers, for yoga-based cognitive intervention. New research papers are solicited through this editorial that examines the neuropsychological effects of demonetization, including the quotient of happiness among the poor and compliant tax payers on one hand and black money hoarders on the other. Another subject of research is the reported disposal of black money in garbage houses and rivers by some, while others adapted to cashless transactions. Such studies can be anonymized by engaging banks where the huge cash of demonetized money was deposited.

#### Funding

No Indian had imagined that the call to demonetize Rs 500 and Rs 1,000 notes by Swami Ramdev, a popular Indian seer, Yoga Guru and untrained scientist, would be reduced to practice by the Indian Prime Minister so swiftly and firmly, in the same generation. Many Indian scientists had started complaining about reduced funding in research. The new financial year now promises increased funding for research and development programs as the government exchequer is once again flush with funds, left dry at the time of last change of government because the

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fund collection in the last 50 days exceeded a whopping Rs 1,500,000 crores (USD 22,077 billion). Some funds can be allocated for neuroscience research in India under "Modi" brain fund.

#### **New Roads for Research**

There is a general perception that the authenticity of data generated from re-emerging economies like India is interpreted with caution. With increased funding, government agencies are expected to mandate implementation of quality assurance programs in Institutes where it provides funds to make data traceable, auditable and verifiable. This will attract more collaborations, joint projects and many more multi-disciplinary, multi-national initiatives for societal good. These can be sourced from "Modi" brain fund.

#### **Integrative Medicine**

The emergence of integrative medicine is necessitated by the growing corruption in medical practice, patient referrals, out-of-pocket expenses and callousness towards complex and incurable disorders. Increased funding is expected to focus on preventive and public initiatives, integration of lifestyle intervention through yoga and alter-

#### Reference

Anand A: Affordable neurogenetic screening as a powerful tool for beti bachao. Ann Neurosci 2016;23:195–196. native therapies which is possible through the establishment of centers of integrative medicine. Since most of the incurable and genetic diseases pertain to the brain and there has been a recent failure of Alzheimer's disease clinical trials in its final phase, the Indian lawmakers are considering centers of integrative medicine to be managed by eminent neuroscientists. The funding can be sourced from "Modi" brain fund.

### **Cash Is King in Conferences?**

Much of the dirty money from Pharma industry finds its way to sponsoring conferences. With increased collection from taxes, the out-of-pocket expenses of poor patients can be curtailed by mandating Institute-sponsored conferences rather than pharma-sponsored meetings. This will help the poor patients to seek affordable treatments and genetic screening for empowering the girl child [1] without having the need to go to private labs for investigations. Enforcement Directorate and Income Tax Departments have so far neglected this field of corruption.

The recent spurt of change in RBI guidelines has cornered the corrupt, similarly rapid changes in rules of governance in medical institutes must be implemented to corner the corrupt medical practices. One way is to erect an interdisciplinary team in the spirit of newly revamped national medical commission (NMC).

# Eye Genetics: The Road Ahead to Quality Standards

Sridhar Bammidi, Kaushal Sharma, Rahul Tyagi, Neel Kamal Sharma, and Akshay Anand

## Abstract

The prevailing system of running research labs in conventional set-ups are based on no uniform method of management, relying completely on individual preferences and experiences. Unfortunately, even the leading institutes involved with research in health and medicine fail to incorporate defined modules unless mandated by the guidelines of GMP, essential for clinical translation. The present trend shows the drop in clinical trials presumably due to inherent questionable data and lack of back traceability of information. The ability to bring clinical level safety at the genetic research level facilitates Quality control measures unique, transparent and credible for clinical translation. Good Laboratory Practice (GLP) modules have been developed to enhance quality standards, increase credibility, efficiency and transparency of research settings. The studies in ocular genetics, pathology, pharmacology require similar benchmarks. There have been rapid increase in the cases of eye diseases in Asia but the process of genetic data generation is not uniform and auditable. The studies involving larger populations include meta-analysis and GWAS etc. which require collaborations, need to be supported by a standardized managerial system. Quality standards define such tools ensuring back traceability, verifiability and auditability of data and test systems. These should also address IP conflict management and implementation of standardized protocols. The quality control

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and GLP can lead to benchmarking of research data which are usually considered a soft activity in Medical Institutes where most of the genetic data is generated. The Quality control practices in such large scale research collaborations require testing the source, prevalence and resulting therapies for overall ocular health.

Keywords

Quality assurance • Good laboratory practices • Eye genetics

Around 285 million people over the world live with visual deficiency. Out of these 39 million people are blind, and 117 million are with uncorrected refractive errors [1]. Most of the blindness is curable. India is now home to the world's largest number of blind people with more than 18 million people who suffer from one or other form of blindness. Genetic factors are important in the development of eye diseases. An increasing number of genes have been associated with eye disorders. The delivery of accurate test results is the most serious problem indicator for laboratories. Presently, practice of medicine has been entirely redefined by the developments in genetic testing. Genetic testing is widely used as common tools by research institutions. However, there is extensive and widespread application of genetic testing and analysis after the completion of the Human Genome project. During genetic testing, there is always a possibility that any systematic or random error may occur and put human health at risk. To categorize and to work with eye genetics, we need to build and improve the quality standards with genetic research and services to achieve excellence.

# 34.1 Quality Throughout the Testing Process

Genome-wide association (GWA) and metaanalysis have accelerated the pace of genetic research in eye diseases. GWA studies are based on analysis of single nucleotide variation in the genome and its association with pathological condition. GWA studies are required to have case and control participants. Case group may be clinically pre-diagnosed, but control group should not have similar disease phenotypes. After the completion of human genome project (HGP) in April 2003, it identified millions of SNP changes in the whole genome which has been deposited in public database "The SNP consortium (TSC)." Two major aspects need to be emphasized in GWA studies, i.e. large population size and large genome coverage. Large population size is important to avoid false-positive genetic association derived by modest p-values for some of the genetic alleles. Similarly, a genotyping array provided by companies (like Illumina, Perlegen, Affymetrix, etc.) does not cover the whole genome. Meta-analysis is quantitative statistical analysis from all the studies done in particular field by combining them all and to draw a precise and effective scientific inference. Meta-analysis shows the presence of heterogeneity by including all relevant studies randomly that could provide impartial and balanced conclusion. Even the studies which have less impact due to less sample size could show up on meta-analysis inference. Metaanalysis studies provide new research question or perspective which assist policy makers to customize new policies/protocols in the research area. Therefore, in both kinds of studies, it is crucially important to have proper guidelines or checklists to improve the quality of such studies, reports, and scientific conclusion obtained from these reports. Here in this chapter, we have discussed some of these issues which should be included while performing such studies.

# 34.2 GWA Studies in Eye Research and Its Quality Control

GWA studies could provide direct relation between disease and genetic changes, which possess powered study designs. There are some limitations in GWA studies, which result in drawing varying inferences. However, we can enhance the quality of GWA studies by considering following issues in various studies.

- GWA studies have defined case-control population in which case could be pre-diagnosed before recruiting them in the study, while control population must not have similar disease phenotypes as case population. There should be proper documentation of inclusion and exclusion criteria in verifiable format.
- 2. Sample size for GWA studies is important since all its inference and conclusion are based on the significant association of SNP variance with disease pathology (p-value). Moreover, there are a few studies which have been retracted from renowned journals due to discrepancies raised by use of different kinds of genotyping arrays. Commercially available genotyping high-throughput array (e.g., Affymetrix, Illumina, or Perlegen, etc.) covers only a small proportion of total SNPs found in human genome. Various arrays used in genotypic analysis have different sets of SNPs, which lead to different inference/conclusions and also have reported various genetic markers in disease pathology. In the Indian set-up, such limitations can be addressed by adopting whole genome sequencing or nextgen seq. method. Additionally, the introduction of statistical imputation analysis in such studies could bridge the gaps for missing genetic links between different study outcomes. The cost of sequencing is now much cheaper and can be made affordable in Asia if quality tools are implemented.
- 3. The whole genome coverage analysis also provides gene-gene interaction and assortment of different genetic alleles in disease phenotypes.

- 4. GWA studies also are not able to describe the cross talk between different diseases and their common SNPs. The pleiotropic effect of particular SNP which affects different sets of other disease conditions cannot be analyzed by GWA studies.
- 5. GWA studies must also have to include some statistical tools that could analyze the geneenvironment interaction and epistasis phenomenon in disease phenotypes. Such problems are being solved by introducing genetic linkage analysis and Mendelian randomization approach.

# 34.3 Quality Control in GWAS

### 34.3.1 Sample Quality

It is very crucial to code the sample immediately on receipt along with defined gender identifier. The chromosomal structural changes and atypical X chromosome numbers can also influence the end point analysis of GWA studies calculated through software. It is very important to code the sample properly and also introduce basic questionnaire, which includes all the basic points like sex and other sociodemographic details of the participants. By doing so, it could reduce the chance of type 1 and 2 statistical errors in final analysis of the genetic data. However, sample identity and kin relation could also be identified by using PLINK software while analyzing GWAS genetic data. Pairwise dot matching in the dot plot of GWAS data could identify unrelated, parental, or duplicate/twin samples by their scoring as 0, 1, or 2, respectively. The graphical representation of the pairwise data can be done through R software [2, 3]. It is also possible that in such studies, an individual can be involved in more than one center in case GWA studies are multicentric. The common method used to identify the ancestor in a large population is principle component analysis (PCA). Therefore, in such cases, the person has to be excluded after software analysis by which we can reduce the type 1 and 2 statistical errors in final analysis.

Additionally, it is also desirable to assign a defined sex or number of X chromosome of the participant so that it may not increase the copy number variance or the SNP's number of total genome as in case of Klinefelter's syndrome (XXY) or Turner syndrome (XO). The X or Y chromosome numbers can be calculated through probe intensity or log-R ratio which is the ratio of a particular sample to total samples. If the value is less than zero, it is considered as deletion in the chromosome, and a higher than zero value could be signified as the duplication of chromosomal genes or nucleotide sequences throughout the chromosome. Considering these issues, the quality of analysis can be enhanced. Therefore, a good way is to maintain a checklist in a lab and ensure periodic orientation of research staff associated with genetic analysis.

#### 34.3.2 Population Stratification

Population stratification is the major problem of biasness in the population-based case-control study, which has different genetic and phenotype appearance [4]. Therefore, it is advisable that the population must be homogenous in nature in GWA studies. True-false association occurs due to the ancestry rather than the true association of allele to disease. stratification in population Small affects GWAS severely because large population size is required to detect common variant of complex disorders [5]. By combining the samples from multicentric GWA study, the complete analysis could result in population stratification. Population stratification could be detected and adjusted by applying genomic control approach [6, 7]. Tools like Eigenstrat analysis [8] and STRUCTURE [9, 10] could be used to address the biasness raised because of population stratification by combining data from different subpopulations and further linked with the data of cohort GWA studies.

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# 34.4 Meta-analysis and the Contribution in Quality Control

The meta-analysis studies provide scientific clues in a particular field by combining all the relevant articles. It provides the precise and effectiveness of the study which had even shown less significance in an individual study. Hence, such studies are very useful in policy making and initiation of evidence-based treatment [11, 12]. As compared to GWA studies, the heterogeneity in literature selection can play a crucial role in conclusion of the study. Therefore, quality control in meta-analysis is an important component in order to provide impartial, balanced, and effective conclusion of the research done in the particular field.

There are some issues that may prevent biasness from the meta-analysis.

## 34.5 Random Selection and Independent Literature Search

A good and independent literature search is important to reporting the accurate conclusion in meta-analysis [13]. Literature search should not be confined up to only single database. Literature search and selection of article could be done on different search engines independently like PubMed or MEDLINE or Embase with three independent key words by each individual author.

# 34.6 Inclusion and Independent Review of Selected Articles

It is also important to isolate relevant article in the study and that should be reviewed by each authors to make their critical comments on inclusion and exclusion of the paper.

### 34.7 Data Extraction

Most data extraction analysis is based on the question to be addressed by the meta-analysis. Therefore, it is necessary in such studies to extract data independently with multiple individuals. It is useful to compare the results obtained from independent data extraction and resolve any divergence in the results or conclusion.

# 34.8 Analysis and Conclusion of Meta-analysis Studies

More rigorous and complex analysis is required in such studies, especially when it includes a large number of studies to avoid biasness in the conclusions of study i.e. there must be heterogeneity in data analysis. Heterogeneity is defined by how many variables are analyzed in the studies in order to make a harmonious conclusion. Heterogeneity could happen at the level of mythology, too. Moreover, the type of statistical analysis could also create statistical heterogeneity. Therefore, in any meta-analysis, it is imperative to report what kinds of approaches have been used in interpretation and analysis of data.

There are several guidelines statements being used. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [14] statement defines the guidelines to carry out the meta-analysis especially in clinical trials. Similarly, Meta-analysis Of Observational Studies in Epidemiology (MOOSE) [15] statement has also described the guidelines for epidemiological studies and their conclusions. These essential guidelines and protocols have also been described in "Cochrane Handbook for Systematic Reviews of Interventions" [16]. Recently, the Quality Of Reporting Of Meta-analyses (QUOROM) and checklist of meta-analysis statement provide descriptive protocol to present abstract, introduction, methods, results, discussion, and conclusion of the meta-analysis studies. It also defines the method of searching, inclusion, and selection of articles. It contains the checklist for inference, data assessment, validation, data

abstraction, and extraction. By failing to comply to the QUOROM checklist, it could enhance the biasness of meta-analysis study.

# 34.9 Confidentiality and Security of Eye Genetic Research Data: A Case for Global Quality Control

Emergence of techniques to explore the human genomic information in order to provide the health care services and for the interoperability of information has increased the vulnerability to privacy breach. Patients' genetic data has direct implications on the family members at risk due to which exchange of genetic information needs to be regulated by timely documentation and installation of tools for protection of privacy, ensuring regulated health-care delivery. There is a need to have global law that ensures compliance by signatory nations so that confidentiality of patients is protected.

### 34.10 Definition of Genetic Research Data

Nucleic acid information includes targeted diagnostics, where a single gene or a polymorphism is evaluated; population-based newborn screening by MLPA, NGS, or PCR; and large scale microarray techniques which screen multiple genes and polymorphisms constituting genetic data. Analyzing human DNA, RNA, and banding patterns that aid in providing diagnostic and prognostic information about an individual or a patient needs regulation because more and more eye-related disorders are being discovered that have genetic basis [17].

### 34.11 Consent for Sharing

Most informed consent forms for data collection state that the information obtained will remain confidential, and it is made sure that disclosure is done with precaution. Though genetic information

## 34.12 Storage

Most of the genetic information is preserved in the form of electronic data, which must be kept in server-based storage, and data accessibility should be strictly through virtual private network (VPN) in the secured network. Server domains are required to be allocated to the staff so that personal confidential data can be stored with restricted accessibility and back traceability.

### 34.13 Good Lab. Practices

Implementation of GLP principles has the potential to develop a system-dependent management besides delivery of diagnostic services and storage of genetic data in the secured places. Some of the GLP practices lacking in India must be followed as below:

- 1. **Master Schedule:** Each research staff could prepare a weekly plan of genetic analysis work to be completed in a month. Master schedule can then be submitted to quality assurance (QA) before the beginning of the month. QA can then review the progress of the research and technical staff at the end of the month.
- Quality Assurance: Independent study, infrastructure and facility-based QA reviews could be carried out once in a month to record and monitor the deviations in genetic analysis. Study-based QA inspections can monitor the work as per their master schedule. Deviations from the master schedule can be documented and followed up in the next month. Independent checks of experiment are carried out to check the compliance to SOP.
- 3. Formulation of Documents: Standard operating procedures (SOPs), data recording sheet (DRS), and raw books can be maintained by QA and provided to research

worker from time to time. Any experimental procedure performed in the laboratory could thoroughly adhere to respective SOPs enabling verifiability and back traceability of data and procedures carried out in lab from time to time. Any deviation can then be reported in DRS as well as raw book which could be the source of information for identification of problems. SOP and DRS should be stored in secured premises. Such systems can automatically impart quality checks at various procedures.

**Standard Operating Procedures (SOPs)** SOP can be prepared to streamline the experimental protocol and make administrative functioning of the genetic unit transparent and auditable. This may include specifications of experiments, along with time-dependent log sheets of chemicals and equipments used in the procedure. It facilitates the system dependence of research workers and reduces the scope of errors or confidentiality breach in handling genetic data of eye disorders. Any experimental and administrative procedure performed in the laboratory should adhere to respective SOPs approved by the management.

**Data Recording Sheet (DRS)** To minimize the procedural errors, DRS could be formulated for the real-time monitoring of genetic analysis. DRS can be prepared in consultation with study director and typically consist of procedures for identification of SOP, patient coding, sample locations, reagents used, and document control with assistance of QA. DRS can be issued only at the time of conducting the experiment and resubmitted to the QA after approval from the study director.

**Personal Discussion and Lab Meeting** A day in a week/month can be allocated to every research worker for quality discussion regarding the genetic testing platform, research problems, progress, and validation of vendors from which purchases are being planned so that there is continuous communication and sharing of information to avoid confusion and mismanagement. **Logbook** Logbooks for each instrument used in genetic analysis could be helpful in not only maintaining the record of usage of resources but also ensuring error reporting and back traceability of data.

**Log Sheet** Log sheets can be helpful in organizing resources and their utilization in a timely manner. This may contain vendor information, expiry date, total amount, purchase information, and stock entry information.

# 34.14 Formulation of Checklists, Price list/Benchmark/ Instrument Files

**Checklist** Checklists can be developed to ensure the completeness of the task assigned to research workers, which compensate for the human limitations. Checklists can be formulated for all of the academic or administrative lab procedures including consent forms, human ethical clearance, and storage of research data as well as confidentiality proformas.

### 34.15 Instrument File

A logbook can be installed along with the instruction sheet and equipment maintenance file applicable to the experimental protocol at hand. Any experimental procedure performed by the use of these instruments in the laboratory can be adhered to, by following the respective instruction sheets. Any deviation can be reported in the logbook as well as instrument maintenance file which could be the source of information for identification of problems in the instrument. Instrument file can include calibration chart; service and maintenance chart; installation, operational, and performance qualifications; instrument manual; instrument password; and information of person to be contacted in case of emergency.

- 4. Auditing: Internal and external auditing of genetic data enhances the accountability and acceptance of the study. The quality assurance (QA) could conduct periodical audit of the progress and compliance and reproducibility of experimental protocol. The data generated can be filed in a defined format using raw book, calibrated instruments (with IQ, OQ, PQ), master code, log sheets, and regulated room environment providing backup for each facility (including power outrage). Validation of data from an independent lab is desirable in order to enhance transparency.
- 5. Archive: The archiving facility coupled with quality assurance program can allow maintainability of important records and samples, thus reducing the time of both the research personnel and patients.
- 6. **Master Coding:** Coding chart can be developed by laboratories to mask the direct sample information in the format, which can be easily decoded. Once a human sample enters in the laboratory, it must be made mandatory to code the samples in order to protect the confidentiality of valuable genetic information.
- 7. **Periodic Meetings:** Research workers who deal with genetic information can conduct periodic meetings to discuss the problems of genetic analysis in the experiments, storage, ethical issues, and compliance to quality control-related issues which can then be recorded and documented in the defined formats to further link the information in the common folders.

### 34.16 Conclusion

Quality control covers periodic training, knowledge of bioethics, confidentiality, and ownership of inventions, which is essential for supervising data quality. With the advancement of highthroughput genotyping and sequencing techniques together with improved analytical methods, the contributions of genetic and environmental factors in the development of eye diseases needs to be clarified. Yet much remains to be explored and more quality control with appropriate applications is needed in genomics so that the data generated is helpful in practicing precision medicine. The ultimate goal is the development of a panel of quality standards for genetic testing in eye disorders in order to improve patient care and research.

### References

- 1. Vision 2020 global initiative for the elimination of avoidable blindness: action plan 2006–2011. www. who.int/blindness/en/index.html
- R Development Core Team. R: a language and environment for statistical computing. R Foundation for Statistical Computing; Vienna, Austria: 2005. ISBN 3900051070, URL: http://www.R-project.org
- 3. Turner, SD. Visualizing sample relatedness in a GWAS using PLINK and R. 2009. https://www.mc.vanderbilt.edu/victr/dcc/projects/acc/index.php/ Visualizing\_relatedness
- Cardon LR, Palmer LJ. Population stratification and spurious allelic association. Lancet. 2003;361:598–604.
- Marchini J, Cardon LR, Phillips MS, Donnelly P. The effects of human population structure on large genetic association studies. Nat Genet. 2004;36:512–7.
- Devlin B, Roeder K. Genomic control for association studies. Biometrics. 1999;55:997–1004.
- Reich DE, Goldstein DB. Detecting association in a case-control study while correcting for population stratification. Genet Epidemiol. 2001; 20:4–16. [PubMed: 11119293].
- Price AL, Patterson NJ, Plenge RM, Weinblatt ME, Shadick NA, Reich D. Principal components analysis

corrects for stratification in genome-wide association studies. Nat Genet. 2006;38:904–9.

- Pritchard JK, Stephens M, Donnelly P. Inference of population structure using multilocus genotype data. Genetics 2000; 155:945–59. [PubMed: 10835412].
- STRUCTURE. 2009. http://pritch.bsd.uchicago.edu/ structure.html
- Bown MJ, Sutton AJ. Quality control in systematic reviews and meta-analyses. Eur J Vasc Endovasc Surg. 2010;40:669–77.
- Garg AX, Hackam D, Tonelli M. Systematic review and meta-analysis: when one study is just not enough. Clin J Am Soc Nephrol. 2008;3:253–60.
- McManus RJ, Wilson S, Delaney BC, Fitzmaurice DA, Hyde CJ, Tobias RS, et al. Review of the usefulness of contacting other experts when conducting a literature search for systematic reviews. BMJ. 1998;317(7172):1562–3.
- 14. Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA. 2000;283 (15):2008–12.
- 15. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. J Clin Epidemiol. 2009;62(10):1006–12.
- 16. Higgins JP, Green S. Cochrane handbook for systematic reviews of interventions version 5.0.2. The Cochrane Collaboration; 2009.
- 17. McGuire AL, Fisher R, Cusenza P, Hudson K, Rothstein MA, McGraw D, Matteson S, Glaser J, Henley DE. Confidentiality, privacy, and security of genetic and genomic test information in electronic health records: points to consider. Genet Med. 2008;10(7):495–9.
- Knoppers BM, Strom C, Clayton CW, Murray T, Fibison W, Luther L. Professional disclosure of familial genetic information. Am J Hum Genet. 1998;62:474–83.



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**Short Communication** 

# Person-Centered Healthcare and Integrated Public Health

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#### **Keywords**

Person-centered healthcare · Participatory action research · Personalized medicine · Patient-centered outcomes research · Ayurveda · Genomics

#### Abstract

The incubation of person-centered healthcare for integrated public health is the focus of this short communication. Here we look at creating an equipoise between culture, medicine, and translational research methods. We propose that these factors can be explored through participatory action research and on-site training of early-career medical professionals. This approach may be one way to build a bridge between trusted tradition and evidence-informed practice. The authors share twelve paths through which integration might occur. They challenge medical professionals to take their places alongside researchers, policy makers, and patients to construct a relevant and practical path that can embrace the rich cultural heritage of traditional Indian medicine with international standards for medical research and care.

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Public involvement in research, healthcare, and self-care is a powerful catalyst for change in the health culture. This requires the integration of healthcare, self-care, and shared data exchange all constructed in a climate of trust where patients and clinicians can integrate modern medicine, traditional care, cultural beliefs, values, preferences, and translational science. In this incubation for integrated public health, informed shared decision making will be within our grasp.

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The public brings to the table valuable perspectives learned from living with the health problems research works to solve [1]. Patients as research partners in the clinic, at home, and in the lab can provide the fine details for a successful implementation that differentiate a

research finding that sits expensive and unused from primary care that improves quality of life [2, 3]. Life experiences can reveal practical wisdom for prioritizing the health questions that matter to patients [4]. It is possible that contributions by patient research partners may go unreported, and this can be compounded by role confusion where the terms "public involvement", "community engagement", "citizen support", and "quantified self-groups" are

Differentiate a research finding that sits expensive and unused from primary care that improves quality of life

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used interchangeably [5]. We know from a multiplicity of research that priorities recorded by researchers on behalf of patients may not be the same as those that are important to patients [6].

Uncertainty in chronic illness is a giant we all face. Currently, the traditional option is to wait patiently in crowded offices where time is at a premium and satisfactory queries to questions of survival and care are rare. The kind of questions patients and doctors both seek are very similar.

This can be captured by these concerns: "where is the problem located in my system?" (doctor's anatomical diagnosis), "why is this happening?" (etiological diagnosis), and specifically "why is the ailment happening to me or my loved one?", "what can be done now to right this condition?", and finally and tragically "why are the medicines not working?" (prognosis) and "what are my other options?".

Patients want to help and are willing to share their experiences and their data, but they

This requires the incubation of person-centered health with public health to increase information literacy

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need assurance their vulnerability will not be exposed to those who can harm them. Most would agree to data sharing with some caveats. People prefer personal data in transferable formats so they can control who to share it with and can download data to share across operating systems [7]. Patients would welcome the appearance of aggregated data, such as a dashboard where they can compare their lives and chosen interventions with the fates

of populations before and concurrent to them. Patients want updates tailored to their needs. This requires the incubation of person-centered health with public health to increase information literacy.

In recent years, online consultations to address these queries have become a trend both among care-givers and care-seekers [8], and yet the current medical education curriculum (whose primary beneficiary is the patient) has not been able to create the kind of knowledge, attitude, and skills necessary for this evolving area [9]. Also one of the reasons why most people are unable to get answers to their queries is because of the paucity of solutions for many chronic, complex illnesses with multi-morbidity in spite of decades of advances in health research. It is possible that "multi-morbidity" is the manifestation of interconnected physiological network processes within an individual in their socio-cultural environment viz. genomic, metabolomic, proteomic, neuroendocrine, immune, and mitochondrial bioenergetic elements, as well as social, environmental, and healthcare networks. The future of "multimorbidity" management might become much more discerning by combining the balancing of physiological dysregulation with targeted personalized biotechnology interventions. These may include small-molecule therapeutics targeting specific cellular components of the stress response. Simultaneous community-embedded interventions that involve addressing psycho-socio-cultural impediments would help to strengthen personal/social resilience and enhance social capital [10].



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Rationale of a proposed incubation center.

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The focus area includes "patient-centered outcomes research," which is an emergent research method evolving since 2010 [11]. This area helps to meet the needs of the patient's requirements and can provide alignment with their personal values. Mobilization and training of human resources is needed to answer those requirements with effectual, practical, and innovative solutions. This fosters social outreach not only to the patients and the individuals seeking preventive therapeutics/practices, but also reaches to the students at primary level so that their minds are ignited at an early stage about the existence of age-old practices, current therapeutic measures, and the history of their evolution as well as the need for innovation.

We aspire to a future where healthcare transformation is developed through shared learning between health professionals, scientists, students/scholars, citizens, and patients with chronic complex illnesses.

We propose to elaborate and objectify these ideals through the construction of incubation centers that may include these initiatives:

1. To involve out-patient departments (OPDs) from leading health institutes and hospitals for the recruitment of complex patients with multi-morbidity in whom modern medical treatment has failed into an incubation center for evidence-informed innovative strategies toward further monitoring and treatment. This recruitment of patients will also involve organizing mega health literacy campaigns free to patients to create awareness about health, help, and available evidence for early detection and treatment. This could be managed with the help of volunteer healthcare workers, technicians, and allied paramedics, exploiting the social skills of non-government organizations (NGOs).

2. To assemble various healthcare systems under one roof (allopathy, Ayurveda, Yoga, genetics, stem cells, and research) for wellness and holistic treatments including teams with respective expertise. One rationale for this is that cultural traditions can be twisted by for-profit junk scientists. The harms caused by this exposure to bad health science can reduce treatment efficacy and endanger patients. In an incubation center, patients can be treated holistically and with full transfer of information between practitioners of each discipline. In this way, case studies, between-person interventions, and even clinical trials can explore the evidence base for complementary and emergent care.

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**3.** In accordance with patient preferences and long-held Indian traditions, it was suggested **patients could be stratified for a regime facilitating categorization** through the doshic and prakriti (Vata, Pitta, and Kapha as outlined by Ayurveda) variations and further implementing these dimensions in personalized medicine. This could form a specialized branch of Ayurgenomics.

**4.** To install affordable, accessible genetic tools for the early detection, counseling, best intervention, and prevention of avoidable disease in vulnerable families.

5. To implement pre-clinical investigations and establish the efficacy of the integrative medications by in vitro, in vivo, and patient-driven research. The study would involve the comparative study between herbals, Yoga, and biologicals and could contribute to citizen science research involvement.

6. Better awareness and management of individual health and illnesses through a **networked system approach to include awareness** about lifestyle and non-communicable diseases and as a center for community-based research and understanding uncertainty and risk. It also involves awareness-based interactive learning for schools and college students as part of the social outreach program of the center.

7. The development of a working model of a "participatory learning ecosystem for practicing evidence-informed multidisciplinary integrative medicine" where instead of just a single doctor, the patient gets the benefit of a global (and local) network of health professionals and scientists (including citizen scientists) who optimize the patient's information requirements in a manner that can influence their chronic disease problem in the direction of positive outcomes. This model facilitates a culturally sensitive, literacy-considerate incubator for testing multi-criterion, analytic, informed, shared decision making that incorporates simple sliders where patients can indicate values and preferences against preset evidence-based algorithms.

8. Employment generation: a large workforce will be **"task-shifting" traditional roles** of "individual patient information communication management". This was till date a preserve of physicians, but it is no longer manageable by them due to the sheer volume of information growth in medicine.

**9.** This system hopes to rationalize healthcare budgets through such measures and by the integration of health learning camps. This will provide a vehicle for **shared recommendations from interdisciplinary panels of experts for the implementation of efficacy and comparative effectiveness rather than the constraints and inconsistencies of consensus by opinion.** 

**10.** In devising a suitable MD-PhD and PhD-MD program in integrative medicine that can showcase **the fruits of the innovative solutions** proposed and developed during the entire project duration.

**11.** In **bringing together** the platforms of data management, patient-friendly open notes for the clinical record, and publications through integrative medicine and neuroscience communication.

12. In teaching the philosophy and Sanskrit for the elucidation and decoding of age-old practices contained in the Indian texts for MD-PhD and PhD-MD students for the better understanding of Indian forms of medicine and integration within the international healthcare system.



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To the best of our knowledge, no conflicts of interest exist.

#### References

- 1 Boote J, Wong R, Booth A: "Talking the talk or walking the walk?" A bibliometric review of the literature on public involvement in health research published between 1995 and 2009. Heal Expect 2015;18:44–57.
- 2 Price A, Biswas T, Biswas R: Person-centered healthcare in the information age: experiences from a user driven healthcare network. Eur J Pers Cent Healthc 2013;1:385.
- 3 Richards T, Snow R, Schroter S: Co-creating health: more than a dream. BMJ 2016;4550:i4550.
- 4 Crocker JC, Boylan A-M, Bostock J, Locock L: Is it worth it? Patient and public views on the impact of their involvement in health research and its assessment: a UK-based qualitative interview study. Heal Expect 2016, DOI: 10.1111/hex.12479.
- 5 Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al: Mapping the impact of patient and public involvement on health and social care research: a systematic review. Heal Expect 2014;17:637–650.
- 6 Snow R, Crocker JC, Crowe S: Missed opportunities for impact in patient and carer involvement: a mixed methods case study of research priority setting. Res Involv Engagem 2015;1:7.
- 7 Price A, Liew SM, Kirkpatrick J, Price J, Lopreto T, Nelken Y: Mind the gap in clinical trials: a participatory action analysis with citizen collaborators. J Eval Clin Pract 2017;23:178–184.
- 8 Purkayastha S, Price A, Biswas R, Jai Ganesh AU, Otero P: From dyadic ties to information infrastructures: carecoordination between patients, providers, students and researchers. Yearb Med Inform 2015;10:68–74.
- 9 Bera K, Seth B, Biswas R: Conversational learning among medical students: harnessing the power of web 2.0 through user driven healthcare. Ann Neurosci 2013;20:37–38.
- 10 Sturmberg JP: Multimorbidity and chronic disease: an emergent perspective. J Eval Clin Pract 2014;20:508– 512.
- 11 Gabriel SE, Normand S-LT: Getting the methods right the foundation of patient-centered outcomes research. N Engl J Med 2012;367:787–790.



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Indian PM's International Yoga Day 2016 Advocacy: Trends, Advances and Future Perspectives

**Editorial** 

#### Indian PM's International Yoga Day 2016 Advocacy: Trends, Advances and Future Perspectives

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The decision of Prime Minister Sh. Narender Modi to role model and advocate Yoga as national health initiative on 2nd International Yoga Day in Chandigarh inspired the local administration to engage citizens and experts in regular yoga training and interdisciplinary dialogue. A series of yoga training programs ensued in 180 city locations and a proposal for analysis of its effects in blood/vitals of these individuals was mooted. Launch of 3D awareness campaigns in the Lake premises and organizing a 4 day national conference 'Yoga for Good life' were the other highlights.

An interdisciplinary conference (June 9-12, 2016) was held in collaboration with Ministry of AYUSH, Mumbai University, Panjab University and Annals of Neurosciences, coordinated by Ms Kirti Garg, Prof Shubadra Joshi and Col G S Chaddha. This dwelled on Yoga's role in Health, Medicine, Profession, Personality, Education and Management. The speakers included Honorable Swami Ramdev, Honorable Ravi Shankar, and Honorable Acharya Balkrishan and was attended by over 300 delegates. Many important policy coordination meetings in the sidelines were coordinated by Dr Jaideep Arya. The proceedings of the conclave are being published in the current issue of International Journal, Integrative Medicine International. Mr Ajay Balaji Joshi, the nodal officer for PM's visit cum Deputy commissioner of Chandigarh spelled out the recommendations of the conclave. These included: inclusion of Sanskrit, Philosophy and Ayurveda in all educational courses in Universities/Medical Institutes as ancient Ayurveda texts, containing knowledge of Indian traditional medicine are in Sanskrit; it was argued that Yoga is irrelevant without its prescription and research in Medical institutes. It was felt that the Depts of Complementary Medicine/Ageing could be established by Medical Institutes so that patients visiting these OPDs have the freedom to choose Ayurved/Yoga intervention under common facility, making healthcare affordable for complex diseases. This will improve quality of medical care and generate comparative data between Yoga and drugs. For best integration, MCI could include representatives from alternative medicine, scientists, patient advocacy groups and quality assurance representa-

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tives. A suggestion for initiating the PhD-MD course in Integrative medicine also came up. The Advisor, Sh Parimal Rai, also reinforced to establish a hospital for traditional medicine in Chandigarh.

The Govt of India had proposed the AYUSH IYD protocol of Yoga to be implemented for the International Yoga Day public engagement. Its effects on vital parameters in a month long yoga practice could be interesting. The Chandigarh administration with support of Bharat Vikas Parishad Charitable Foundation, Joshi Foundation and DGHS, Dr Vanita Gupta and her team plan to study such effects.

The retrospective analysis of Chandigarh based healthy yoga trainers, who were engaged in such a huge exercise, could provide interesting data from their health profiles, if analysed.

When healthy naïve Yoga trainees were introduced to Yoga as run up for the International Yoga Day, some of them volunteered to undertake General Health Questionnaire, before PM's Chandigarh's visit on June 21. The analysis of the health profiles of several of these naive yoga practitioners could generate new data and opportunity for scientists to undertake future studies based on large public exercises like this. Majority of the public practised AYUSH mandated Yoga protocol between 6-6.45 am. The biggest display was at Panjab University grounds where participants came in huge numbers and appeared euphoric after 1 month of yoga practice. Many variables can be analysed after more time to see if this can protect them from complex diseases, if they continue the practice of yoga. The trainers reported that yoga volunteers felt relaxed, slept well and could concentrate better after 1 month of yoga and wanted to continue Yoga for a longer time. Many of them are still continuing to do Yoga in Chandigarh parks which can still be seen flooded with neo Yoga practitioners. The preliminary observations reveal that there was a general trend towards increased health consciousness in Chandigarh due to PM's impending visit. This brought people closer to Yoga. These observations were based on compliance to daily attendance, of both trainers and trainees, which was monitored by the organisers to ensure PM's public Yoga engagement. Long term controlled studies are needed to examine if yoga's preventive impact on degenerative diseases lasts until old age.



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Fig. 1. Prime Minister Sh. Narender Modi on 2nd International Yoga Day in Chandigarh.



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Indian PM's International Yoga Day 2016 Advocacy: Trends, Advances and Future Perspectives

#### New Tools to Probe Ancient Technique

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**Background:** Yoga has been claimed to have beneficial effects on health and disease. This is often eclipsed by limited imaging, biochemical, clinical and neurophysiology studies. The preventive effect of Yoga remains undeciphered due to absence of molecular, longitudinal and comparative studies. This is further perpetuated by cognitive bias against Yoga in medical practice.

**Purpose:** The aim is to highlight the hurdles impairing advancement of knowledge of yoga's non pharmacological effects in disease prevention, health economics and cure. One of the causes is its dissociation from modern medicine and Pharmacology. Hence, there is need to undertake longitudinal controlled studies in healthy individuals that are followed up until ageing. This can be done by not only using genomic, epigenetic, bioenergetic and proteomic tools, in both somatic and gamete genomes, but also by its systematic integration with medical education and research so that comparative data is generated.

Methods: Responders versus non responder phenotypes after standardised yoga protocol is implemented, need to be segregated based on carefully defined inclusion, exclusion and diet criterias. This can only happen when independent Interdisciplinary Departments of Complementary Medicine and/or Ageing and Memory, under Ministry of Ayush, are established in Medical Institutes. Funding of new centers in such Institutes can be made conditional to inclusion of Ayurveda in medical curriculum, just like Chinese Traditional medicine is included in Chinese medical curriculum. This is possible by either inventing PhD-MD programs in Integrative Medicine, establishing innovation clinics or by replacing MCI by an interdisciplinary higher education board represented by various councils like MCI, Quality Council, Research Council, Medical Engineers and patient support groups.

**Results:** The Indian PM's sustained mobilisation of Ministry of Ayush has raised hopes that new investigations, policies and deliberations are able to bring transformational change in the medical landscape. Through such means, these re-emerging therapies can become new tools for saving health budgets. Intolerance of Pharma industry/academia towards Yoga as public health initiative, needs pragmatic solutions.

**Conclusions:** True impact of Yoga in wellness can only be realised by recruiting faculty from alternative medicine in each Department of Medical Institutes. Their integration with modern medicine need to be monitored by Ayush representatives in Institute bodies and ethical committees where new study programs are processed for approval.

Keywords: Yoga, AYUSH, Research, Non-pharmacologic effects.

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#### Ayurgenomics for Predictive, Preventive and Personalised Medicine

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**Background:** There has been worldwide resurgence of interest in Ayurveda/ traditional medicines both amongst scientists and society. Increase in the prevalence of common complex disorders like cardiovascular, metabolic, neuropsy-chiatric etc with their long term medication and adverse drug reactions has compelled the the health researchers to look for novel strategies to control/reverse them with standardised

and validated treatment protocols. Purpose: Ayurveda, ancient Indian system of medicine that forms a living tradition of health and healing even today, has a basic tenet of predictive and personalised approach in preventive and curative medicine. It discusses the management of health and disease not only with medicine but also through diet and lifestyle modifications that help maintain/restore harmony between individual's internal and external environment. According to Ayurveda, the basic constitution of an individual called as 'Prakriti', to a large extent determines one's susceptibility and progression to diseases and their response to micro-macro environment. Prakriti of an individual remains invariant throughout lifetime. It is developed as a consequence of relative proportion of Tri - Doshas - Vata (V), Pitta (P) and Kapha (K), in the parental gametes at the time of fertilisation and is also influenced by maternal diet, lifestyle and environment. It can be assessed through clinical examination of a person considering age, ethnicity and geoclimatic conditions in the background.

**Methods:** We have developed a framework for integration of Ayurveda methods with genomics and modern biology called 'Ayurgenomics' for validation of concepts of Ayurveda and discovery of genetic markers important for adaptation, disease susceptibility and response to therapeutics. Using this approach we have earlier been able to identify gene and genetic variation important for high altitude adaptation and hypoxia responsiveness.

**Conclusion:** In CSIR-TRISUTRA, an inter-disciplinary networked center for Ayurgenomics, we are primarily carrying out *Prakriti* based stratification of normal healthy individuals of diverse ethnic and geo-climatic conditions in

# Editorial

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# Affordable Neurogenetic Screening as a Powerful Tool for Beti Bachao

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Genetics is the study of genes and genetic variations in living organisms. Genetic variations in complex diseases can be tested using sophisticated molecular tools developed by scientists over the years. Despite the success of the human genome project, the potential of this technology for the *Beti Bachao* program remains underrepresented in government hospitals and medical institutes.

For example, Duchenne muscular dystrophy (DMD) is a fatal incurable disorder of dystrophin gene abnormality. It is inherited in the X-linked recessive fashion, thus affecting only the male child. This means that it does not manifest in female mothers because they possess the extra gene copy (XX) to shield the deleterious effect of the defective dystrophin gene. However, this is not the case in males where it expresses it, leading to the fatal disease. Interestingly, the disease also has a higher incidence in India, up to 1 in 1,400 as compared to global figures of 1 in 3,200, with bulk of the rehabilitation work (read alternative therapies) being carried out by non-government organizations such as Indian Association of Muscular Dystrophy in the North India and Molecular Diagnostics, Counseling, Care and Research Centre in South India. Several experts continue to insist that neurogenetic diseases are no longer rare, and therefore their social and economic impact is enormous. The X-linked recessive pattern of inheritance makes the females susceptible to becoming an invisible carrier of the disease, thus increasing the probability of her offspring to be affected, with up to 25% DMD sons, and 25% daughters as carriers, and 50% offspring remaining unaffected, if not screened promptly. The rural and/or urban poor women (especially, DMD mothers) who do not have access to affordable genetic tests in government hospitals remain uninformed about their impending vulnerability. Prevention options for the families are, therefore, critical for the management of this incurable genetic disease so that death and misery do not spread any further, and DMD mothers are not ostracized in the family or society. The consequences can be disastrous in our patriarchal society, especially when this DMD mother has to bear the pain of seeing her DMD sons die in her lifetime apart from being forsaken by her husband.

These women can be mapped for a follow-up so that there is complete integration into a socially secure environment. This is also required because the identification of female carriers of deletions/duplications of the DMD gene is crucial for preventing the birth of children affected by DMD. By ignoring the potential of molecular techniques in government hospitals/institutes of the region, known for female feticide, there is looming risk of unmasking the vulnerability of carriers of genetic disorders.

The views expressed here are personal and do not represent those of an organization or any office or position held by the author.

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E-Mail karger@karger.com www.karger.com/aon Akshay Anand PGIMER Chandigarh 160012 (India) E-Mail akshay1anand@rediffmail.com This can be prevented by carrier screening, pre-natal screening, and pre-implantation manipulation. SAARC countries and African nations face similar challenges, where access to genetic testing is very expensive or limited. Developed nations face a different kind of challenge due to the high cost of genetic testing (up to USD 1,500), which Indian institutes provide for a mere USD 20. This is also an opportunity for globalizing India's genetic testing outreach and capacity building if the new Medical Education Commission, set to replace Medical Council of India, is represented equally by individuals from medical, scientific, patient groups, engineering, economics, and AYUSH backgrounds to achieve an integrated healthcare system. This can also save the deprived sections of the society, especially female carriers of affected dystrophin gene, from impending exploitation and ridicule.

Such free genetic screening measures for detecting female carriers can become an important aspect of *Beti Bachao* policy of Government of India, partly experimented by Joshi Foundation that organizes such health camps that seek to integrate genetics with modern and traditional medicine. These health camps are socially effective for poor carrier females (DMD mothers) who are otherwise left to bear the brunt of politics of referral to private centers.

Mandatory nationwide launch of genetic testing service units by scientists in the tertiary care hospitals can not only promote *Beti Bachao* campaign in a scientific manner, but also preserve the genetic database which can be exploited for bio terrorism. This can best be achieved by establishment of Centers of Integrative Medicine within the Medical Institutes.

# excellence in medical research - can we make it in india?



#### Introduction

The health-care system across the world has witnessed a phenomenal improvement so that the life expectancy in almost every country has

increased significantly. Besides improvements in public hygiene, the newer noninvasive methods of diagnosis, newer drugs and unprecedented technological advances in treatment and patient-care have all contributed to the longer life span. This puts further demands on applied research for developing new drugs, tests, imaging techniques, surgical modalities etc, especially because the increasing population burden and longer lifespan have generated novel health issues that were not so critical even a few decades ago.

The recent unprecedented progresses in our understanding of Nature, biological systems and the amazing technologies now available to common man give an impression that we have solved most mysteries of the Nature's laws and principles that govern us. Armed with this belief, most of the economically advanced countries have placed priorities on "applied research", especially in the biomedical field, in order to ameliorate the increasing load of old age and life-style diseases. With detectable improvements in the overall performance of scientific research in India, it is often asked if India should also not place greater priorities on applied research in Medical Institutions.

#### Basic research as tool for transforming medical practice

Basic research in bio-medical field is usually understood as a tool to help unravel the disease mechanisms and identify drug targets through genetic and/or biochemical analyses. Such studies are generally carried out by MSc-PhDs. Ability to reading the human genome fuelled ideas that we understand most human disorders and therefore, can develop and apply personalized medicine. However, a deeper probing compels us to ask if we have really learnt enough about Nature's laws and life processes? A serious reflective thinking makes us realize that a very long path still lies ahead before we reach even near that goal. Consequently, concerns are already being expressed in the US and other developed nations about the wisdom on relegating basic research to non-essential, and therefore, avoidable entity. India has so far followed a balanced view and not succumbed to oft repeated question as to why we should spend limited resources on basic research. While technological advances appear stupendous and attractive, one must not forget that their roots are deeply embedded in knowledge gained through basic research carried out by passionate people whose only objectives were to unravel mysteries of nature. Only when the "mystery" becomes "knowledge", we can apply and exploit it. Mysteries of Nature continue to exist and baffle us and, therefore, stimulate basic research. Newer basic findings in conjunction with appropriately developed technology leads to affordable and integrative healthcare.

#### Where are the roadblocks?

While basic research efforts have generally been supported in India, we have not had many breakthroughs, either in biological or in physical sciences. Unfortunately, as a nation we do not also have many technological advances to our credit. Obviously, there is something wrong in the system, notwithstanding the large human and other resources being used in the process. Paradoxically, Indian scientists outside India have been doing very well and make us proud but when it comes to 'make in India', we are not able to feel the same sense of pride as most of the drugs, diagnostic kits or equipments used in healthcare are made outside India, including in China. Obviously, besides the limited resources, we have more serious systemic issues that underlie the country's generally poor performance.

# Overburdened with patient load or human resources or both?

Our medical institutions, medical colleges as well as the mandated research institutions, are expected to be actively involved in research since all MD, MS, MCh, DM aspirants are required to carry on some "original" research and submit a thesis for earning the degree. In addition, the various regulations for appointments and promotions require research publications as essential components. Several institutions have also introduced MD-PhD dual degree programmes beside the PhD programmes. Thus, there is, in principle, a sizeable work force in place for carrying out research in the medical colleges and institutions. Unfortunately, only a small proportion of this large work force has the opportunity to work at places with fairly well-equipped infrastructure. Most others work under rather difficult conditions including very long continuous "duty" hours. They are also constrained by inflexible time-limit for completing the "research" component of the degree. A continuity of research is also not maintained so that each new student works on different topics rather than extending the theme where the previous one had left. As a result, the research output remains rather disappointing and the enormous advantages offered by the human resource on one hand and the diversity of Indian population on the other is almost completely lost, and we continue to rely, for diagnosis as well as prognosis, on data generated in other countries with very different genetic and physiological backgrounds.

The formal teaching load of a typical medical college faculty is usually not as high as those teaching in basic science departments in a university or college, although in most of the clinical disciplines, teaching continues in OPDs, wards and on the operation table as well, somewhat parallel to "teaching" that goes on in basic research labs. A common explanation for the rather limited novel research output from medical institutions is that the medical college faculty members have patient load amidst meager infrastructure which leaves them with little time and energy to think about any serious research. This may possibly be true to some extent for faculty in clinical disciplines at a medical college attached to big hospital. However, the medical faculty in better endowed medical institutions may not be engaged with OPDs/surgeries or wards on every working day and, therefore, the average per week workload may not be exceptionally or unduly high.

This may be due to large number of physicians in such Institutes. Compared to

the many private/corporate hospitals, faculty positions at publicly funded medical colleges generally fare poorly in terms of service conditions, salary/promotions and facilities. Existence of significant disparity amongst different state and central institutions, poor infrastructure for research in medical colleges, inevitable bureaucracy associated with administrative issues of running hospitals, all add to the medical teaching institutions becoming less favoured places of work. This adversely affects the academic output of the institution.

Medical colleges generally seem to have a strong hierarchical and authoritative setup. This thwarts the enthusiasm of young and capable faculty who wish to go beyond the routine health-care. A healthy academic and productive environment demands equal participation, incentives and opportunities for research.

#### Collaborative involvement of basic scientists in research, administration and policies relating to medical research

Medical institutions also have "non-clinical" or "para-clinical" departments/units whose faculties are not directly involved in clinical practices or patient care. Unfortunately, even their research output is also generally not impressive. At the same time, the administrative dichotomy created by differential privileges and responsibilities of the "clinical" and "non-clinical" faculty members remains a major cause, often unnecessary and avoidable, for heart-burn and conflict that affects basic as well as applied bio-medical research in medical institutions

Notwithstanding our ad libidum appreciation of practices followed in western countries, we have kept the medical education and research separate from basic sciences as well as technology. On the other hand, almost all the leading biology departments in US universities are parts of Medical schools. Although models for integrative learning and teaching have been frequently discussed in the country and many detailed reports prepared, the fact is that we continue to ensure compartmentalization and fragmentation that percolate down to the smallest unit possible. Absence of integrative research with collaborative basic science leadership remains a major impediment to 'Make in India' based innovation in Medical Institutions.

In the context of "conflicts" between "clinical" and "non-clinical" or "basic"

scientists in our medical institutions, an idea has sometimes been mooted that the country should have "Basic Science Council" along the lines of the existing "Medical Council", "Dental Council", "Pharmacology Council" etc. However, whether establishment of such councils and formulation of rules will solve the conflict or promote any better research environment remains to be seen. An example of well-meaning but poorly formulated and implemented rules that result in more serious ill-effects is the introduction of the "Academic Performance Index" by the University Grants Commission to ostensibly promote academic activities. Paradoxically, these measures have generated more graft than promoting any better academic environment or performance. Thus even well-intentioned rules can become counter-productive when driven in the wrong direction.

It is indeed a sad commentary on the state of affairs that while we have not been able to make significant inroads in modern medicine, we have also failed to capitalize on our age-old health-care system of Avruveda, in spite of our sense of pride at the great wisdom of our far-removed ancestors. As discussed elsewhere, including in these pages (Lakhotia, 2013, Ann Neuro), Ayurveda continues to suffer because of want of serious unbiased inter-disciplinary research, which alone will help us understand its principles and to resolve between myths and reality. It is notable that Chinese have smartly integrated Chinese Medicine as part of formal Medical curriculum. Such integration in Indian context can be promoted by inclusion of multi-disciplinary basic science experts together with practicing clinicians in various committees, governing bodies and other advisory bodies of Ministry of Health and Family welfare.

#### Basic scientists and clinicians as complementary stakeholders in medical education and research

How do we initiate and establish a more stable and interactive dialogue between the clinical and basic scientists and also involve technological experts in translating basic bio-medical research into real applications? One of the steps initiated in recent times to bring in some integration is the introduction of M.D.-Ph.D. dual degree programmes. However, it is not clear as to how these would be qualitatively different from the regular MD or PhD dissertations, since such programmes do not ensure interactive participation of basic and medical scientists, especially when PhD-MD candidates are rather rare (Anand and Rao, Ann Neuro 2014). In any case, what we need are long-term research collaborations on specific themes which, on one hand generate new basic knowledge/databases and on the other promote better health-care or usable indigenous technology.

Creating positions of basic scientists within the medical colleges/institutions, who lead well furnished and independent laboratories, can provide opportunities for MD/MS/DM/MCh as well as PhD students to work under joint supervision of Scientists and medical faculty. Physical placement of such labs within the medical college/hospital is expected to facilitate better interaction since the clinician can walk in any time for interaction with scientists, who can similarly walk to OPDs or surgery tables. Such basic research scientists can guide and monitor "directed basic research" in identified core areas that impinge on basic health-care in the country. A model of "directed basic research" was initiated some years ago. with success, to revive understanding of the basic science underlying Ayurveda.

Recent years have witnessed an increasing number of better equipped corporate health-care systems with lucrative paypackages. These are good destinations for utilization of basic science research skills but have remained untapped. With increasing involvement of the better equipped corporate sector in health care, it would be prudent to engage them into a public-private partnership so that they function as technology incubators utilizing research outputs from both public and private medical institutions.

Initiating teaching programmes which involve co-participation of basic scientists and clinicians is another avenue that fosters sustainable partnerships. An example is the discipline of Human Genetics. An increasing proportion of contemporary health issues centres around genetic factors. Unfortunately, the medical curriculum does not adequately prepare the medical doctors to understand the complexities of genetic disorders, their diagnosis and possible treatment. Formal co-training of science students by basic scientists and medical professionals, through didactic lectures, would not only prepare appropriately skilled human resource, whose demand is continuously increasing world-wide, but would also foster a better dialogue between the basic scientists and medicos. The Molecular and Human Genetics MSc programme started at the Banaras Hindu University about 15 years ago is an example of such success story. Next step in this direction should be to prepare courses for Genetic Counselors. Equally rewarding would be development of training and research programmes in metabolomics and microbiomes, which have also become hot areas in contemporary health-care.

Appropriate changes in the archaic rules that govern medical education and profession together with active participation of all concerned would make a value addition and generate the much needed manpower to collect and understand data for genetic and physiological makeup of Indian populations. Such data are essential to provide "Make in India" health care in the country.

#### Conclusion

Medical research is not singularly poor in our country. We have less than impressive performance in other spheres of research, innovation and technological development. The poor performance of medical research, however, has more serious repercussions since it directly affects health of people and therefore, of the nation. Obviously, we need to ensure quality medical research on a much larger scale. More than rules and regulations, what we really need to achieve these goals include: i) commitment and passion, rather than compulsion, for research and innovation combined with necessary mentoring, ii) bi-directional interactive and integrative environment that promotes and sustains collaboration between clinical and basic scientists on one hand and the technologists on the other, who can convert innovative findings into usable technology for affordable healthcare, iii) good training of medical students in clinical research especially for those who are inquisitive and research-oriented and iv) adequate independence of doing research to take their discovery to masses.

There is an element of "conflict of interest" when it comes to considering the medical profession as a profession that is directed solely to treat patients and earn the livelihood in return. It is argued that to be able to get into active clinical profession, which usually implies obtaining super-specialization degree, the young person has to spend many more years of life, often under rather unpleasant conditions, than is the case in other professional courses. Therefore, they feel that they are entitled to greater monetary rewards than the NPA available in most academic institutions as a compensation for losing on private practice. Such disgruntled persons cannot obviously give their best just like those basic scientists who seek introduction of non consultancy allowance (NCA). New salary structures of medical faculty. normalized to per hour risk free engagement, is often argued to provide remunerations equivalent to private centres. A substantial increase in the NPA or introduction of NCA for basic scientists may, therefore, not be the best or lasting solution. As long as we do not develop a system of identifying the right kind of human resource for a given job, such conflicts of interests and poor outputs would continue. Just as every MSc or PhD degree holder does not by default become a scientist, a basic medical or even a super-specialty degree would not generate a medical researcher. While we need a large number of researchers in the bio-medical fields, we need equally large numbers or more of medicos to attend to basic health issues in rural and semiurban areas. Therefore, what is required is to identify and promote the young aspirants into paths that better suit their temperament and capabilities than stereotypes. There is no point in trying to fit square pegs in round holes or vice-versa. Facilitation of suitable matches and optimally promoting their activities is essential for us to really make excellence in India.

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# National model for replicating benchmarking of basic research investigations in govt institutes: a case for ministries of science and technology and health and family welfare

"Good Laboratory Practices (GLP)" enshrined under the OECD guidelines provide an excellent framework in raising the bar in research productivity in our country. Ironically, none of the publicaly funded labs in the country have adopted these norms for basic research investigations. If these norms are adopted it may result in enhancing the quality standards, increase credibility, efficiency and transparency of research and diagnostic facilities. This is the first time that the Neuroscience Research Lab at PGI chandigarh was awarded National Award by Quality Council of India for implementing quality principles voluntarily. This innovation has led to a system dependent technical and managerial procedures facilitating research audit and document control, improving purchase and accounting procedures as well as human resources besides delivery of patient care diagnostic services.

The conventional system of running research labs in India is based on no established or uniform method of management relying on individual preferences and experiences. Unfortunately, even the individual medical institutes do not define modules of running research facilities unless mandated by GMP requirements defined by regulatory authorities. This happens in the case of clinical trials where patient's safety and care is involved. These trials have been presumably halted due to questionable data and lack of back traceability of information. The ability to bring clinical level safety at the pre-clinical (basic research investigation) level makes this innovation unique transparent and credible for effective clinical translation. This can stimulate knowledge economy and attract huge investments from around the globe.

The current quality systems in Neuroscience Research Lab encourages goal driven, self proposed monthly master schedule of activities in consultation with the study director, using the combination of Standard Operating Procedures (SOPs), Data Recording Sheets (DRSs) and master schedules. The Quality Assurance (QA) conducts periodical audit of the progress, compliance and reproducibility of experiments giving a new lease to research output. The data generated is filed in a defined format using a mandatory raw book, master code, calibrated instruments (with IQ, OQ, PQ), log sheets with continuously regulated infrastructure and room environment providing back up for each facility (including power outrage). This data and samples (if any) are archived in defined shelves or freezers as the case may be so that research productivity and quality is enhanced. The electronic repository of entire data is maintained in dedicated servers secured by physical installation of firewalls.

The entire system in the research facility operates under a moral obligation for biannual external audit by senior quality assurance experts which includes proficiency testing. This innovation encompasses periodic training of research personnel and staff to not only engage in academic activities but also bio waste management, sanitation, fire extinguisher safety, firsy aid, animal handling, and development of IQ (Intelligence quotient), SQ (Spiritual quotient), EQ (Emotional quotient) through periodic orientation programs which are essential for mentoring of independent neuroscience research leaders for tomorrow.

This innovation aims to enhance the reproducibility and error reporting of

research data and sustain quality system in research practices, thereby facilitating a higher sincerity of purpose for research in medical institutes in India. This system also seeks to bridge the credibility chasm that exists between data generated from India and that from the West, because of which the best research from India is rarely taken seriously. The frequency and quality of research papers from this research facility provide for an innovation which has improved the credibility of research generated from this research facility. This is expected to boost discoverv and innovation thereby accelerating translational research.

Implementation of this concept has led to benchmarking of research projects which are usually considered a soft activity in medical institutes of India, thereby enabling reliable translation of bench to clinic. This innovation has led to a system dependent technical and managerial procedures facilitating research data reproducibility, audit control and document control.

It is a perfect time for new Ministers of Science and Technology and Health and Family welfare to take note of this and consider instructing the funding agencies like DST, DBT, ICMR, DAE, DRDO under them to demand quality systems to be implemented in labs before releasing tax payer's money to them for research and development. Neuroscience Research lab can be converted into a national reference laboratory to mentor this activity.

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**Akshay Anand** 

Editor in Chief

# need for innovation in medical institutions

Practice of Medicine is rapidly changing the health seeking behavior around the world, however, an important aspect of this field hasn't changed in India. For instance, we have not witnessed credible translation of medical training or knowledge into indigenous solutions for surgical modalities or diagnostics. Can we do something about bringing transformation in order to make larger impact on Indian society? Let us discuss the various models of how to fill that big gap: the distance between competence and excellence, and how by doing so, one could attempt to amplify the efforts through multi disciplinary patient centric approach.

#### **Overcoming stereotypes**

There are a number of things that one is taught which are believed to be correct at the time of medical training. However, much of it has the possibility of being incorrect as one begins to test waters in real life. Avoiding the trap of thinking that one knows everything as well as projecting this to patients as such generally helps one excel and maintain an honest relationship with patients. Therefore, carrying the amber of doubt in the practice of medicine is the key to advancement in the field. For the very reason that doctors are often perceived as having certain stereotypes: all knowing, upright, trustworthy, clever, conservative, authoritarian etc, as medical students, one may have pressures to conform to one of these stereotypes. One shouldn't. A lifetime spent trying to become something you are not may destroy you. Being oneself and trying to learn steps that help bridge the gap that separates one from simply being competent to being excellent and innovative is the basis of originality in research and translation. One of the recipes to instill innovation is also to become investigative, carrying the amber of doubt while accosting every patient in a clinic or ward. There are many thinkers that argue that doctors should even share their ignorance with patients and together help patients overcome their misery. Evidence shows that genuine partnerships with patients generates better outcomes and greater satisfaction for both patients and doctors.

#### Innovation

Medicine is not only clinical work, it is much more: working out relationships, teamwork, communication skills, research, innovation, publishing and critical appraisal. With the amber of doubt one is more likely to discover new clinical associations, syndromes, and solve problems that medicine had never previously resolved. However, such efforts require multidisciplinary approach that should include individuals from basic sciences, engineers, MBAs and even patients. Some of us wonder why is this important when rush of patients need to be immediately addressed. This editorial is an attempt to argue that a link exists between such innovative endeavours and value addition in practice of medicine. As mere glance at the make of hospital instruments or prescription of drugs reveals that most of these are imported, invented by individuals outside India. India pays a huge cost for buying these drugs and instruments in the form of inventorship costs i.e patents acquired by scientists who are not resident Indians. These individuals have even gone out to win Nobel prizes in Medicine. Eventually, the cost of import combined with commercial cost of patents held by these individuals (read countries) is recovered from the end user i.e the patients. If the these individuals could be one among us, being passionate about converting the zeal into undertaking that journey between competence and innovation, such inventions could transform the Indian medical world. This is possible in collaboration with other stakeholders in healthcare systems such as Pharmacologists, basic scientists, venture capital and engineers. Such models have capacity to drastically reduce the healthcare costs directly affecting the costs of healthcare delivery. This is exactly why many of us argue research and innovation as the potent tool to advance our knowledge economy (or health economics), in whatever way one puts it.

There are limited number of innovators in India such as Dr. Sathya Jeganathan who invented low cost incubators, Dr. V Mohan who spearheaded mobile telemedicine clinic, Dr. Prakash Khanzode who invented affordable patient beds and so on. There are even student role models who have published over two dozen articles in international Journals while in final year of MBBS. However, such examples need to increase in numbers. Kalam-Raju stent is another example of home grown stent which could not have been possible without residents not taking such an initiative outside immediate call of duty. The ability to say 'Yes' to opportunities outside immediate world of clinics and surgeries and venturing into medical innovation may add even great value to the healthcare landscape in India. It is time that our residents and trainees step out of the routine medical world and play 'larger' role in patient care through innovation driven entrepreneurship.

#### Research learning cycle

Learning is the basic ingredient for innovation. Orthodox learning may have stopped for us today, with acquisition of degrees, however, neither us nor our senior teachers can claim to know everything. They are still students as much as we are and are still learning. There are many methods of learning that are available in the field of medical education and depending on the one you adopt, you can make bigger impact in your field. Conversational or blended learning involves combined interaction and discussion at multi disciplinary level which has often been advocated to result in innovative spirit and should therefore be encouraged. Every patient, for that matter, can be regarded as a learning material as well as a research project that requires one to pause, listen and investigate, treating a patient not as organism replete with similarity of symptoms that characterize a certain disease, instead, one with a unique phenotype. Documenting and building patient data and compiling various investigations from various patients examined, may result in generation of new knowledge that can be useful drug trials and systematic reviews of tomorrow. These ideas can also become the grant applications seeking research funding from funding agencies. The colleagues in research learning approach could become our collaborators and the data we generate can become original research papers and patents.

Applying such knowledge for innovative solutions to existing clinical situations may then lead to discovery of new drugs, surgical techniques or diagnostics which is what India needs today at an affordable price in order to transform its healthcare infrastructure.

#### **Nobel Prizes**

At this point it would be pertinent to be introduced to the world of high achievers most of whose research and innovation has transformed healthcare. Analysis shows that majority of Nobel prizes, constituted by Alfred Nobel's foundation, to reward the outstanding contributions towards mankind, have been won by individuals from West. Closer analysis also shows that average age of research productivity of these Nobel Prize winners peaks at 35-45, which is the age we reach in a couple of years after getting the regular tenure track. With an award coming from Alfred Nobel's will, each prize continues to approximatea staggering USD 1 million. Many surgeons and physicians have distinguished themselves by winning Nobel Prize in last few decades. These include Prof Banting (for Insulin), Prof Yamanaka (for induced pluritotent stem cells). Prof Mansfield (for MRI) etc. With arowing number of MD Nobel laureates the national focus has shifted towards capitalising the potential of the physicians and surgeons so that they could convert clinical knowledge into innovations. Such innovations from India can have immense ripple effect on patients whom we have not even seen. This was also the reason cited by Prof Yamanaka when he described his shift in focus on medical research (than just clinic) while choosing to work with induced pluripotent stem cells and providing a technology to convert skin cells into embryonic like stem cells, a feat that won him the Nobel Prize in 2012.

These efforts could not have been possible but for a care for quality work: generating data that is authenticated, test samples which could be back traced and records and investigations which could be audited. In other words implementation of quality systems is the heart of innovation. Working in an accredited hospital is a definite advantage for those clinicians who wish to organize their time well. Those hospitals who do not have such systems should implement such guidelines in order to bring more transparency and quality in practice of medicine. Medical students should similarly participate in activities of quality clinical care. Collaborative spirit combined with inter disciplinary pursuits in Medicine is the only way one can bridge the chasm that separates competence and excellence.

#### Mentorship

Mentoring requires a big heart and passion to derive pleasure at one's trainees surpassing our own professional expertise. The joy of celebrating colleague's success is not experienced by each one of us. Only those who have crossed that vital bridge separating mediocrity from excellence experience such a bliss. We should aspire to reach that stage from where we do not envy anyone, from where we are able to disseminate knowledge, wisdom and share experiences.

Last, but not the least, it is important to emphasise the value of creating female medical leaders in the field. With their increase in the field, very few have reached the top managerial positions. Even reviewing the gender based winners of Nobel laureates, only 85 out of 823 Nobel Prizes have been found to belong to females (with Madam Curie topping the list). This needs introspection. Studies have also shown that female students do exceedingly well in their academics but are reluctant to take up leadership positions in academia and innovation enterprises, leaving enough scope for filling the void. Female medical students should therefore seize the opportunity and lead the field by participating in innovation endeavors so that the mankind can benefit from their intellect, compassion and integrity.

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#### **Akshay Anand**

Editor-in-Chief

# medical education and training: implications for india

The Curriculum

Unlike other countries in the World, MCI regulates a centralized curriculum for the undergraduate and post-graduate courses. In the US and UK, deciding the medical curriculum is the prerogative of the Universities. Medicine has a vast and comparatively wider array of subjects to be studied. These subjects have both clinical and non-clinical distinctions.

In undergraduate studies, the students are exposed different subjects, which are divided based on the hours of lectures. case studies and practical hours. The sole dependence of the undergraduate students rest on their respective professors, who remain busy practitioners burdened with administrative duties. This makes it very difficult for the students to get their queries and doubts cleared. The nonclinical departments like Anatomy, Physiology, Biochemistry, Pharmacology and Microbiology, where theory is emphasised, are being slowly phased out in the West; replaced by elements of genetics and molecular biology but nearly 1480 course hours have been dedicated by the MCI for the practicals in such subjects. Is it worth it? This uneven and insufficient cocktail of subject-exposure deprives the students of both clinical and research expertise. The undergraduate students are rarely posted to emergency wards and therefore lack the knowledge of how to deal with critical care. Many argue that there should be a proper interface between the teaching module by balancing patient contact and associated classroom teaching. Learning the diagnostic and interventional techniques can be brought about only by the contact with the patient and in-ward studies. The teaching and interpretation of further diagnostic measures like Case study, Report study, Therapeutic learning, history taking skills and short listing of differential diagnostic measures can be carried out in class rooms. In the situation where there is lack of facilities and resources it has been seen that peer-assisted learning provides a tangible solution to the problem of clinical teaching skills to a very large group of students: Indeed, it is a norm worldwide. This can work quite well in the medical colleges in small cities with comparatively less busy work environment but can (.....continued from page 133, 20-4)

prove fatal in the present day case scenario wherein the senior medical students are insufficiently and poorly trained. The undergraduate students should be posed with questions based on the cognitive skills and problem solving exercises from the case studies. Perhaps, age old memory based MCQs should be replaced.

The emphasis on problem based teaching, case based questionnaire, clinical-rounds, distinction in class room and in-ward based teaching and developing a centralized promoting examination could prove to be a vital checkpoint for the eligibility and accuracy of the medical graduates. As quoted by Sircar: When an ill-trained MBBS doctor begins his independent private practice, he poses a greater hazard to the patient than the ailment he purports to alleviate.

Some of the deficits in skilled human resources can be overcome by astute planning and by way of integration of nursing services with the medical curriculum. It is almost a requirement in a resource starved country like India that the semi skilled individuals are trained in primary health care and mobilized for health care, especially for rural health care. The deficiency of medical health workers can be met by upgrading the training and standards of paramedical and nursing care. The nursing community worldwide, is fairly experienced and well equipped with various medical procedures like deliveries, midwifery, vaccinations, first aid, primary infections like cough, cold and fever and can perform small interventional surgeries like removing foreign bodies from the eye and nose etc. They can act as full-fledged doctors and take care of the ground level requirements and ailments of the medical field at the primary level. This is very well elucidated by the example of Norwegian nurses running a hospital successfully.

The gaps in teaching because of the time and staff bound discrepancies can be tackled by the intervention of IT in medicine. Training programs and classroom based courses could be launched through internet portals, as already followed in the west. Such a model has been developed by Prof Rakesh Biswas and widely known as the user driven health care system developed at Bhopal's People Medical College. Diplomas involving Telemedicine, Teleradiology, and other paramedical courses could be encouraged as much as courses on Translational medicine as discussed below.

There needs to be re-organization of fee structure in medical colleges. The imposing of heavy Fee-structure on private colleges and relatively stringent regulations have not been matched by fees in Govt Institutes that are purely funded by national tax collected from various states. Like the West, a medical graduate student could be encouraged to pay up for the undergraduate fees and repay it at a flexible rate of interest once he/she begins to earn. The in-service internship mandating service in the villages and remote areas by Ministry of health and family welfare is an admirable step in this direction. This will not only encourage the optimal utilization of tax payer's spending in healthcare but also retain the health workers in the country who begin to write ECFMG tests soon after being trained from national resources.

# Mobility between medical and research fields

As elucidated earlier, both undergraduate and post graduate students lack the complete knowledge about the pathophysiology of ailments and this leads to incompetence and lack of innovation in diagnosis and therapeutics, thus impacting sustained enthusiasm in treatment of patients. Opportunities for both MBBS and MD/MS students should be provided to pursue core biomedical research. Both clinical and non-clinical residents should look forward to research as a new frontier for translating knowledge for better affordable healthcare. Likewise, non-clinical researchers i.e. PhD trained personnel, pursuing core scientific research, should exhibit equal enthusiasm in pursuing MD under a two year hospital training under innovative "to be launched PhD MD programs" and advance knowledge for utilization in health care delivery or translational research. Of course this will require bold changes in policy. Tailor made jobs should be simultaneously implemented in research or medical institutions at the faculty level such that these uniquely trained individuals could be recruited after completion of their courses.

#### Encouragement of medical Entrepreneurship

Innovation is the key to deliver affordable healthcare products in any developing country, including India. Entrepreneurship has a major role to play in medical education in India. Innovations combined with entrepreneurial strategies can bring about a radical reform in reviving the economics of medical education. New healthcare products could be generated as per the needs of the country which should be cost effective and consumer friendly unlike the international and multinational brands. There is an urgent need to include training in innovations in medical entrepreneurship. This can be achieved by chalking out a vibrant program developed with collaboration of technology incubators from different disciplines with the help of industrial tie ups.

#### Human resource management

The biomedical engineers and lawyers are exposed to labor-management or resource-management at some stage or the other. The knowledge of medical professionals is limited by the exposure to manage patients on an individual basis without much exposure in professional management. There is generally no lateral advancement of knowledge among medical graduates for the administrative acumen applicable to medical education and training. The Department Heads in general need to manage the paramedical staff, medical staff, healthcare and diagnostic duties based on adhoc experiences rather than a structured module.

In already resource starving situations, the lack of vision of deployment of skilled resources in optimizing OPD productivity requires the statutory bodies to review inadequate allocation for human resources for patient care. The above problems can be sorted out and optimized by involvement of educationists, professional managers, physicians and social activists. An assurance of the quality in management of medical institutions can be achieved by the audits of the performance of health care workers. Recently, Times of India published an interesting analysis of working hours of senior physicians in National Medical Institutes, arguing that majority of faculty at such institutes has considerable time for innovation and research. owing to a few OPD hours as per week. due to rotation duties coupled with innumerable vacations, conferences etc. An annual audit of deployment of healthcare workers should be implemented either centrally or by an institution which should govern the smooth running of the hospital based on patient feedback.

# Re-organization of medical education managers

Keeping into view the drawbacks in the current managerial system in the publically managed medical education systems, there is an urgent need for reorganizing the panel. The medical education managers and the board need to be re-organized. The panel should constitute members from different spheres rather than medicine alone. A medical institution is a site with plethora of activities with different elements of society working hand in hand. Hence, a proper reconstitution of the statutory body is urgently required. The people form different spheres who constitute the panel, with qualifications as diverse as MD, PhD, Judiciary, Law and civil society have now been incorporated in the newly reconstituted MCI.

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# recipe for translational research in INDIA: MD-PhD or PhD-MD?

The current scientific scenario in India overemphasizes translational research without highlighting need to bring educational and training reforms that can enable such translational research. It is widely believed that there are two cycles of translation, namely T1 cycle which is characterised by bench to bedside approach and the T2 cycle which is characterised by bedside to bench approach. Both cycles are complementary for translational enterprises and are key to raising the basic research investigations for societal benefit. The huge investments in biomedical research are driven by tax payer's money and therefore constitute a precious national resource which needs to be moderated by effective and long term research planning of human resources. The best medical universities outside India have overwhelmingly introduced the concept of MD-PhD program in order to focus on the T2 variant of translational cycle. This is undeniably a significant part of translational research wherein clinical observations define the research goals engendering discoveries in diagnostics and therapeutics. This educational system has led to training of Physician-scientists who are able to reduce the clinical phenotype using the molecular tools and exploit the biological phenomenon that addresses clinical phenotype. Such top to bottom approach is not only essential to apply the imagination of physicians as this platform provides them with the dynamic link between clinical and molecular association but also enhances clinical skills. While India is poised to emulate this model in medical institutes, US, UK, Japan, Europe and Australia have already successfully implemented this exciting career advancement scheme for physicians such that their knowledge can integrate the molecular techniques for clinical benefits. Despite all the euphoria, the pace of

discovery and innovation of biomedical sciences fades to insignificance when compared with pace of innovation in engineering sciences. It is almost negligible in reemerging economies like India. Is PhD-MD the solution to current crisis? How does PhD-MD program offer new perspective than MD-PhD program? Let us examine the differences. The PhD-MD program pertains to the T1 cycle of translation and serves to exploit the expertise shared by majority of research workers worldwide who work outside medical institute i.e. university, research institute and colleges. These venues lack interface with clinical colleagues and are therefore deprived of the elements of T1 cycle and can thus become useful participants of T2 cycle. The PhD-MD program is therefore argued as the most suitable for the countries of developing world especially India, China, Brazil and South Africa. These countries lack the medical facilities. human resources and are overtly dependent on the import of medical devices and drugs which make the healthcare delivery less affordable for their respective populations. It is here where the PhD-MD program can bridge the deficit and successfully develop knowledge equity by accelerating the T1 cycle of translation. This bottom-top approach is characterised by reductionist to clinical visualisation of biotechnology applications thus enabling the bridging of chasm that exists between reductionist approach and systems approach. This is abysmally lacking in the rudimentary MD-PhD program which starts from clinical observation and later examines the molecular details. The information cascade emanating from molecular investigation to clinical observation is the vital link of the complete T1-T2 cycle of translation. Launching of PhD-MD program is also economically viable for developing country like India which needs to develop quality care physicians founded on the sound track record of research than guality researchers founded on sound medical knowledge. The number of Ph.D scientists working on biomedical related problems is growing significantly in India over the last decade. However, most of them do not have an exposure to human anatomy and physiology. This exposure can appropriately equip biomedical scientists to make an impact on translational health research. The PhDs in India are recognised worldwide and many of them can be trained in a sizeable portion of medicine to achieve this goal. They can even be used for serving the rural healthcare sector for such countries with little more training rather than exporting them to sophisticated research labs of the west. A similar pattern did happen in the late 1970's and 80's when a number of Indian Ph.D's working in U.S.A. acquired M.D degrees in Mexico and South American countries. Many of them continued with clinical practice while some returned back to academic research. Although several efforts are being made to start M.D/Ph.D program in India, no significant progress has been made in this direction. Perhaps the alternative Ph.D-M.D model can be implemented so that we can have excellent translationally driven biomedical researchers in the country for the future. This can also be even an complementary model rather than an alternative model to M.D/PhD program.

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# stem cell entrepreneurship in India: trends and advances-I

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India's growing investment in stem cell research is powered by its economic growth and vision to acquire global leadership in biotherapeutics. The recent economic boom in country has been mildly shaken by its overdependence on outsourced service industry and investment from multinational companies which is unlikely to continue indefinitely. It is therefore prepared to overcoming the challenges once represented by the absence of consortium of IP attorneys, clinician-scientists and venture capitalists, the key elements in biotechnology entrepreneurship, so that the economic progress is sustainable. The signs of reversal of brain drain, which once affected value creation, are now becoming evident induced by schemes such as the DBT-Wellcome alliance. However, there are a few academic problems such as authority patterns, lack of performance based incentives and seniority over merit dogma, once an accepted part of Indian academics, that is now being reviewed so that the institutional and faculty support systems become more vibrant and responsive to innovation systems. In this article, the historical and socio-cultural influences that have shaped lifesciences in India have been discussed which include the contemporary academic challenges confronting the biomedical entrepreneurs. We also provide a projection of future growth prospects of stem research translation in India in the context of existing regulations. The framing of ICMR-DBT guidelines for stem cell research and therapy in India is pivotal to the future stem cell therapy is likely to hold for this country and the world. The health and science managers in India realize that India must rely on its own capacity for innovation than depend on MNC outsourced model. This will require more drastic policy changes in the manner that facilitate scientific temper, output and entrepreneurship.

India has a unique combination of ancient knowledge base and modern technology in order to foray into science business. The traditional system of imparting knowledge in India always consisted of free education in *Gurukul* (free residential school).<sup>1</sup> Some thinkers believe that the genesis of the problem of dissociation of wealth creation efforts from knowledge lies in the known relationship problems between Saraswati and Lakshmi. The idea of science entrepreneurship has thus never visited the political thinkers, policy makers or the biomedical scientists until verv recently. In addition, majority of the research in India has continued to be supported by only public funds, because of which the licensing and protection of patents has remained under government control and commercialization of scientific enterprises required bureaucratic clearances. The absence of strong domestic academic pressure groups and private sponsored research entities has contributed to lack of awareness about the business prospects of the scientific ideas.

#### Policy reforms

The advancement of science, particularly stem cell therapeutics has coincided with the shared thrust of national leaders such as Ex President scientist Dr Abdul Kalam and economist Prime Minister Dr Manmohan Singh for pushing knowledge economy. Rapid scientist awareness campaigns have been launched in the country, medical tourism being promoted apart from increasing the R&D outlay. The recent example is the Indian Council of Medical Research (ICMR) which spearheads stem cell research activities in India. It was recently upgraded as a Department of Ministry of Science and Technology, almost doubling the budget allocation for medical research. Several knowledge parks, technology incubators, medi cities and Public-Private Partnership (PPP) projects are being initiated. A technology development board, a national body which oversees value creation projects has been actively promoting science entrepreneurship. The situation at the medical institutes is particularly alarming where there is a need for integration of health and science policy for potential research. The plea for optimal patient care is often justified as an excuse for neglecting the importance of innovation in such Institutes. As a result, the opportunity of translating the developments in stem cell research are lost because of separating clinical practice from basic research. In view of the current over-restrictive policies of US and Europe, there are opportunities for India to maximize the utilization of its human resource and encourage biomedical scientists to participate in generation of new clusters of stem cell research and therapy so that the unmet global demand for such services in the country can be provided in a careful and regulated manner. In order to understand the context in which the current innovation policies are placed in India it is pertinent to review the cultural background of Indian society which shapes the local intellect. Indian civilization is more than five thousand years old and pursuit of knowledge has always been considered central to most Indian households. Indian history of science began in 2000 BC when treatises in astronomy, mathematics, logic, medicine and linguistics were documented. However, at the heart of India's poor record at patenting and science entrepreneurship lies such profound disdain for the idea of commercializing knowledge. The first idea of commercializing knowledge changed when Chanakya, an erudite scholar from medieval period propagated "Arth Kevichaye Vidya" (wealth from knowledge). Yet most of the modern scientists such as JC Bose or CV Raman continued to refrain from accepting financial gains from their research. Today, there is growing realization that India is paying a huge cost for becoming only a user of IP than its generator. It has, therefore, decided to make huge investments in development of stem cell technology and serve local, national and International demand in the field. Fortunately, harvesting Embryonic Stem (ES) cells from in vitro fertilized egg for possible treatment is not considered as seriously problematic as the use of biologic science as the commercialization tool. Interestingly, none of the national or regional political parties have voiced any reservation against the use of this technology. However, for any model to serve these markets successfully, it is important if experimental therapy is not slipped to those who have scant knowledge about stem cell biology, instead such centers should be carefully regulated with the help of qualified professionals that build the critical mass of medical specialists and biotechnologists who could finally participate in such form of therapy.

The flurry of activity that followed the 2004 success of Korean scientists led Canadian parliament to approve the use of excess embryos. Sweden followed by announcing that it would allow cloning of embryos for therapeutic purposes and UK approved a private firm to carry out the generation of ES cell lines. Similarly, Singapore earmarked \$300 million for a technology park centered around exploitation of stem cells. Stunned by the Korean fraud, India took a cautious step by quickly promulgating ICMR-DBT draft, which awaits revision, on stem cell research and therapy so that the research is adequately regulated in this country. The regulation pronounces its expectation by stating that such research and clinical trials are conducted in a responsible and ethical manner, which comply with all regulatory requirements. The provision for separate mechanism for review and monitoring of stem cell research and therapy in the field of human stem cells, one at the National level as National apex committee for stem cell research and therapy (NAC-SCRT) and the other at the Institutional level called Institute Committee for Stem Cell Research And Therapy (IC-SCRT) has been made. The guidelines set out that all clinical trials with stem cells shall have prior approval of IC-SCRT and Drug Controller of India. These regulations provide for stamping out small clinics that promise big hopes without credibility and infrastructure and skilled stem cell scientists and pave way for registration mechanism with central bodies. There are some banks being run from homes and these regulations call for all cord banks to be registered with DCGI as per guidelines applicable to Blood banks. Separate mechanisms for setting up International collaborations for stem cell technology have been outlined and serve to be a big boon for those stem cell entrepreneurs and their western partners that possess requisite expertise and venture capital. There are several

mechanisms for soft funding available in the form of Biotechnology Industry Partnership Program (BIPP) scheme launched by the Department of Biotechnology that funds upto \$2 million. Such level of investment is happening despite the major expenditure being earmaked for defence in the face of cross border hostilities and rising global terrorism. For past two decades the R&D expenditure had never crossed 0.84 % (Das, 2004) of GDP with food and primary health care being the only goal of successive governments, however, it is now expected to go up at least 3 times in the next fiscal year. One of the determinants of the success of such stem cell business is the human resources. A special effort for attracting new brains in key sectors has been proposed by the sixth pay commission, the central body that reviews salaries for all government employees every decade. Govt has planned to expand the lifescience research by adding more institutions. A stem cell research center is coming up in Bangalore that will carry out research employing about 40 faculty members and participate in clinical trials in collaboration with Christian Medical College, Vellore. The Indian Institute of Science Education and Research have been opened at several places across India. Many think it is the exposure of graduate and undergraduate students to the institutes that may bridge the physical gap that existed between the colleges and Institutes. The govt's policy to promote stem cell research in the manner that ensures safety and efficacy of stem cells is likely to facilitate the unparalleled growth of stem cell industry that is likely to serve International clients.

#### Social and cultural factors

Indian life science labs and companies are run by graduate students with very few post docs. Young people are assaulted daily with symbols of India's emerging middle and upper class wealth advertisements of luxury apartments, brand new shopping malls, new cars, International vacations etc. Young people and their families want to be part of this new economic prosperity, and the surest path for a bright student to achieve a comfortable life style is to seek a IIT-MBA program or obtain a job in the IT sectors but this does not include biological sciences. Indian parents continue to hold the keys of their children's future by aspiring through their kids.<sup>2</sup> A majority of them actively participate in planning their future course of studies irrespective of their aptitude. Untill IT-MBA boom, it was fashionable to secure the careers of their kids by pushing them either into medicine or engineering careers. Due to competitive nature of IT, MBA, medicine and engineering courses (which require huge infrastructure but limited seats), only the most meritorious students with better resources and opportunities were able to compete successfully, leaving the others with alternative careers. As a result, a second tier of brains entered life sciences and hence the quality of research output in medical institutes declined. There are comparable trends in some countries but the problem is more acute in India. These challenges remain to be addressed by the policy managers and can be achieved by revamping the organization and education structure and by making research more lucrative, rewarding and interdisciplinary.

Today, the hype created by stem cell research can be positively translated into dream stem cell centers where research and clinical trials can go hand in hand and by not only catering to a very large segment of incurable degenerative diseases but also by the attracting first tier brains into the field. The linkages between investment in research and rationalization of treatment costs on one hand and its expansion through entrepreneurship models needs to be highlighted by science managers. The stem cell research regulations in India boasts of far more liberal policy when compared to USA or Europe and hence provides a unique opportunity of acquiring leadership in the world. Medical tourism which is being actively promoted by the government may benefit from this branch of medical therapeutics. Fortunately, there is no social, religious or cultural barriers that can halt the stupendous advancement in stem cell therapeutics in this region. Such an environment is conducive to build an International team so that the liberalism of Indian laws could accelerate the advancements in stem cell therapies.

#### Economics of Reductionism

Wealth creation from Biotechnology,

particularly stem cell technology involves heavy investment in the form of infrastructure, equipments and biologicals for which India pays a heavy price as IP user. Even the cost of accessing electronic knowledge resources is very high apart from the cost of patenting itself.<sup>3,4</sup> It is estimated that only 5-10 % of patents are eventually commercialized and hence recovering the costs requires capital. It is seldom realized that the huge cost involved in buying research consumables are directly proportional to the IP value of the product. National development research council (NDRC), Technology Development Board (TDB), ICICI science park and technology incubators are fast coming up to facilitate technology commercialization with the help of venture capitalists. This is important because lack of indigenous IP increases the cost of technology that the country will end up paying escalating the investments in research. Therefore, in effect, the costs of research itself continues to grow driven by continuous import of equipments of research. As majority of the scientists work in public funded centers, a vast majority of innovative scientists remain clueless about concepts of science entrepreneurship as there is no visible provision to create spin offs while being in government service. As the government conduct rules do not allow holding of two simultaneous jobs, forming of spin off company until recently was an impossible task. A mechanism of encouraging in-service scientists to form a company either by proceeding on sabbatical leave or by providing consulting services can change the landscape of innovative efficiency. The Indian PM has recently signed a regulation allowing in-service government scientists to hold equity in a company directed by him. This is being recognized as a major paradigm shift in Indian sciences.<sup>5</sup>

Until recently, India has witnessed a huge cash inflow and funds are not difficult to obtain. The multinational companies are also investing in knowledge parks and collaborating with Indian institutes, establishing their own manufacturing plants in India and hiring Indian scientists at good salaries. The range of opportunities the stem cell application is likely to create in future will depend on local investors and by serving the International patients who desire to obtain stem cell therapy but cant obtain it their own country due to stringent laws. Such profits will stay as long as those governments do not reverse their overrestrictive policies.

#### Academic Challenges

Whether the rapid brain drain from the country is affecting wealth creation in the country is hotly debated. On one hand the Non Resident Indians are able to transmit money back to their home country enhancing the foreign exchange while the research centers are not able to exploit their talent for national growth. The onus lies on the academic institutes and the policy makers to retain this intellect. There are now attractive schemes such as those floated by Department of Biotechnology (DBT) to recall the scientists who have left the country. DBT is offering them attractive incentives and facilities through Ramalingaswamy fellowships. Provisions for joint faculty between US and India and between the various departments within the country can greatly boost such efforts because this not only promotes scientific collaboration but also enhances innovation capacities by networking. The dual citizenship scheme propagated by Ministry of External affairs has become very famous for this reason, particularly among Non Resident Indians. Academic challenges lie ahead in bringing organizational changes. These include establishment of business development offices to encourage science entrepreneurship, especially in medical Institutes. This can save the Institutes from high rates of attrition. The lack of appreciation of the value of interdisciplinary research is another challenge, which the medical Institutions are finding very difficult to recognize. Many of these challenges can be addressed at the root level by promoting science fairs in schools, enabling mentoring opportunities for young kids and establishing science museums in as many cities as possible. This can instill scientific temperament among kids. This is central to stimulating the young minds at the right time. DBT recently organized a business proposal development competition for science scholars, which created a lot of enthusiasm among young minds indicating that there is potential for engaging scientists towards marketoriented research.

The organization of awareness fairs, workshops and training programs will be the key in overcoming the political, organizational, social and economic hurdles towards shaping research efforts by science entrepreneurship model. The sustained change in paradigm of its education, innovation and commercialization policies with enhanced outlay in R&D can promote the growth of IP generation and commercialization for economic growth. Concomitant investments from private institutions and/or alliance with medical institutions can catalyse the generation of spin offs by the biomedical scientists. Since Indian economy is growing at a good rate of 9.4 % there is huge potential for both commercialization of IP and its consumption. A colloquium of lawyers, scientists and policy makers is a requirement that can strengthen the current innovation policy. This can facilitate the exploitation of the intellectual capital lying untapped in this sub continent. A lot of people believe that lack of accountability is the heart of inefficiency of scientists. It may be pertinent to stamp out the permanency of government jobs and enhance accountability through regular science audits. At such point, it is pertinent to make the academic institutes financially autonomous by allowing them to generate and survive on their funds. This will enhance accountability and only the meritorious faculty would be able to lead such Institutions.<sup>6</sup> The need for some sort of distinction between the hard working faculty and mediocre workforce needs urgent attention. The rapid advancements in the area of stem cell research has the potential to make India as an international capital of stem cell research therapy.

(To be continued...)

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# ANNALS

#### References

 Saraswati Shantipriya Pandit. A critical study of the contribution of the Arya Samaj of Indian education, Ph.D Edu., MSU, 1974-2.

2. Kakar, S., 1971. Authority Patterns and Subordinate Behavior in Indian Organizations. Administrative Science Quarterly, 16(3) pp. 298-307.

\_ \_ \_ \_ \_ \_

 Schwartz, D.G., 1995. How physicians and biomedical scientists in India learn information-seeking skills. Bull Med Libr Assoc.83(3):360-362.

4. Anand A. Science entrepreneurship

challenges and opportunities. Journal of Public administrations and policy research 2009;1(1):1-3.

- 5. Anand A. The long and short of it. Annals of Neurosciences 2009;16(2):45.
- Sarbadhikari SN, English D. Merit, seniority and science. Annals of Neurosciences 2009;16(2):46-47.

# India as the potential headquarters of International stem cell research

Stem Cells and Policy was adopted as the focus of the Journal to fill a specific need. The identification of human embryonic stem cells by Jamie Thompson in 1998 ignited an almost unbelievable series of events that at that time and encapsulated the stem cell scientific community in hype propelled to the status of dogma with little if any experimental evidence. This hype resulted from 2 key events. One, the failure of genetic engineering left a void that scientific entrepreneurs rushed to fill. The time was ripe, as the aging population of the United States and other countries sought endlessly for longer, healthy lives. Many of these individuals are and remain very wealthy, and are willing to spend enormous sums of money on any hope of avoidance or cure of disease. Second, the connotations of the meaning of the word "stem cell" was not at all clear, so this cell was elevated to the status of a cell that could restore any lost cell, regenerate any tissue and cure most diseases. This thought seemed to derive directly from the basic qualities of a "stem cell", that quality being that the embryonic stem cell, derived directly from fertilized embryos, indeed generated during gestation all of the component parts of the human organism. This being the case, surely the cell would regenerate parts lost to disease of assault after birth and provide a cure for diseases of aging. These thoughts were not unsupported. Shortly after Dr. Thompson's identification of the human stem cell, Dr. John Gearheart led individuals to believe that these cells could restore intact function of a severed spinal cord. The literature became replete with anecdotal as well as preliminary supportive data showing utility of stem cells in diseases ranging from cardiomyopathy to diabetes. No disease was immune; stem cells could do it all.

Surveying the literature and failed clinical trials, the focus for *Annals* of *Neurosciences* was developed to provide a different forum, one where dogma developing too rapidly could be challenged;<sup>1,2</sup> one where reasoned investigations and interpretation would lead to advance, albeit not overnight.

However, in the United States and elsewhere, profit motivated corporations began to sprout and advertised the potential of stem cell therapy to an overly receptive audience, including members of the press. No one was particularly interested in hearing reality; a frenzy developed wherein individuals almost unaminously held dear the promise of stem cell research, and many invested their careers as well as capital in this potential, thought to be assured. When ethical considerations led to deterrence of embryonic stem cell research, investigators actually used this as an excuse for not quickly reaching the goals they promised, and soon developed alternative sources of stem cells which they held out as equivalent cells to attain these goals. Lost in all the hype, fury commotion and fame bestowed upon stem cell researchers was the simple fact that in no case did stem cells restore or regenerate any tissue in adults, nor did they cure any disease. Every advancement was hailed as a remarkable achievement absent the promised attainment of any clinically applicable therapeutic goals.

As investors questioned the attainment of promises, advances were sought with a fury unprecedented in the history of science, Many of these were said to become clinical realities soon, and an eager public kept the field active. We found many studies of stem cells indeed afforded new thoughts and models of development, and highlighted these as we questioned studies that claimed therapeutic success. The latter have not been realized and the reason for this is the haste of investigators to make claims based on flimsy and irreproducible data, claims that were highlighted in high profile journals. Amidst all this fury was one simple fact; the tremendous motive to attain success obscured interpretation of data of key trials and led to a shotgun approach, rather than a well thought out plan to alter conditions and interpret data accurately. Of all the manuscripts we received Stem Cells and Development, the manuscripts received from India presented a striking exception to this rule.

These manuscripts from only a few centers were reliable, not over interpreted and offered new approaches that we thought may lead to success, but not overnight. These facts and others led us to propose India as the center of International stem cell research. This proposal was greeted with surprising enthusiasm by many investigators throughout the world. Recent therapeutic successes in India support our reasoning in this regard and we stand by our hope that this proposal is successfully adopted throughout the world as failures due to rapid and over interpreted experiments still predominate the field. Recent results from India show that a rigorous, scientifically based and carefully interpreted approach will lead to further success.

#### Economics of Investment

Wealth creation from technology--- one of only a few exportable industries-- involves heavy investment in the form of infrastructure, equipment and reagents. While India has set the standard for economic development as a result of their investment in technology, the cost of accessing electronic resources is very high when initially compared to the revenue initially gained. For example, the cost of patenting and deploying new developments in electronic technology reveals that as few as 5-10 % of patents are eventually commercialized; hence recovering the costs requires capital and it requires manpower and time. With regard to the latter, India in collaboration with US firms very quickly developed an electronic infrastructure which indeed sets the example that serves as a model for development of other technologies. In addition, as outlined by one of us, the costs of research itself grows as it continues,<sup>3</sup> this growth being driven by the continuous need to import state of the art facilities and equipment. However, in the end, the investment has paid off in a major way as India's economy outsteps many economies of developed countries. Thus Prime Minister of India recently signed a regulation allowing in-service government scientists to hold equity in companies under their purview. This is recognized as a major paradigm shift in Indian science, and sets the stage for a similar investment in stem cell research. However, the medical institutions are still left clueless as to how to implement this regulation that has seen cabinet approval. A new order of leadership in these Institutions akin to one conceived by famous Valliathan report is urgently required to propel India to lead stem cell translation. Interdisciplinary leadership such as one seen in Department of Biotechnology (DBT), the major funding agency for stem cell research, and National Brain Research Centre (NBRC) could be extended to medical Institutions.

Until recently, India has witnessed a huge cash inflow taking place, funds were not difficult to obtain. Most of these funds are derived from multinational companies investing in knowledge parks and collaborating with Indian Institutes to establishing manufacturing plants in India. These corporations hired many Indian scientists at good salaries. The range of opportunities the stem cell application, if correctly developed, is likely to create will depend on providing health services national and International patients who desire to obtain stem cell therapy but can't obtain it in their own country due to over-regulation. Such profits will stay as long as those governments do not reverse their overrestrictive policies.

#### Political considerations

Despite India's booming economy, the major expenditure continues to be reserved in India for defence. With rising global violence in the form of terrorism, India is constrained to earmark a big share of its resources in defence and for fighting terrorism. The Indian government's policy to promote stem cell research despite other national priorities in the manner that ensures safety and efficacy of stem cells is likely to facilitate the unparalleled growth of health industry, results of which are starting to make headlines in the world.

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#### References

- 1. Anand A. Journal needs aggressive policy. Annals of Neurosciences 2009;16(1):1.
- 2. Anand A. Raising the bar Annals of Neurosciences 2010;17(2):51-53.
- Anand A. Science entrepreneurship challenges and opportunities. Journal of Public administrations and policy research 2009;1(1):1-3.

# raising the bar

This is probably the first time that the Academy's Journal is making serious effort to acquire leadership in Neuroscience Journalism by sharing editorial responsibilites with counterparts outside Indian origin. The journal which has continued to be published for last 16 years, 4 times a year is now set to overcome barriers that lie in the way of local journals attaining national and global leadership in Neuroscience. l took over as Editor in March 2009 after which all the efforts have focused on enhancing visibility of the Journal. It was soon realized that the impact of Indian Journals, in general, and their citations has never been adequately addressed in this country<sup>1</sup> and, in general, do not match the International standards. Many argue that it is the reluctance of the Indian scientists to communicate their research results to local journals which has led to low citation of these journals. As a result the best research gets known by people outside India before it is even communicated within local journals, others believe that these Journals are not attractive venue for submitting articles. It is believed that scientists communicate those articles to these Journals that have either been rejected from International Journals or those that they themselves regard as second grade. The recognition of this problem by Annals of Neurosciences is thus very timely,<sup>2</sup> particularly when Chinese and European Journals have begun to take a lead in developing their indigenous journals and communicating their best publications in their own journals. Under the guidance of the Editorial Board, a strategy has been laid out to enhance readership by introducing new sections that will make a lasting impact on Indian and world neuroscience.

Promoting new support systems in Neurosciences

Annals of Neurosciences aims to lead the transformation of scientific environment in the country, counter the issues raised above by highlighting the thoughts that capture the hearts and minds of neuroscientists; by publishing articles that do not merely communicate research but also focus on issues that transcend mere acquisition of technology or establishment of new centres in India, those that promote value of human resources in advancing neuroscience research, by re-evaluating leadership roles of Neuroscience programs in the National Institutes, creating new publication/peer review ethics and set ethical standards for other Journals in the world and advocate new funding mechanisms. It also seeks to become a vibrant platform for advocating legislations in stem cell translation and therapy by promoting active role of young scientists and corporates in National Academies, Institutes, National task forces and Journals, and by publishing articles that defy dogma and promote policy research such that the impact of Neuroscience research is felt in our immediate society. This may lead to increased allocation of funds for Neuroscience. Therefore, publication of articles that promote Neuroscience outreach programs and lead to creation of more Foundations and Endowments that sponsor such efforts will ultimately promote solutions to diseases of Brain besides stimulating knowledge economy. Such issues are being covered under 'New Focus' section of the Journal. In my first editorial I announced its new focus to be on Neural Stem cells and Neuroscience policy. The commentaries are attempting to provide insight about how research structure should be revamped

discussing the implications of the new regulation allowing scientists to start their research companies representative of enhanced Academia-Industry partner-ship. Many of such articles have also argued the urgent need to promote young leadership in academics.

# Focus on multidimensional scientific communication

The release of various issues in 2009 have witnessed new design, content and layout and the Journal now finds itself ready to take on the other regional journals including those from China, Japan and several other countries who have built their research around local journals. We introduced some new sections such as 'molecular shots' which features immunostaining pictures; 'Journal Club' which publishes commentaries by graduate and post doctoral students apart from routine research articles. 'Book reviews', 'Commentaries' and 'New Focus' section has also been introduced such that there is multidimensional flow of scientific information. We also published, for the first time, the disease biography of Stephen Hawking, the leading cosmologist who also suffers from ALS alongwith a commentary on his disease by Prof Walter Bradley. Such patients narratives are regarded as important tools of inspiring and promoting Science. Prof Bradley earlier raised questions about Hawking's ALS diagnosis in this commentary, due to the lack of documented evidence from Stephen Hawking's personal release, but later while reviewing the biography, he agreed with the symptoms associated with this disorder. This feature is a revolution in Neuroscience journalism, declares Dr Bradley stating that Annals will acquire leadership in this area and will continue to attempt to bridge the chasm that exists between the diseased and those who run the labs to study diseases. The October issue of the Journal has published a commentary from Tom Isaacs, the co

founder of Cure Parkinson's Trust in UK, on the need for innovation in Parkinson's disease highlighting the need to integrate and empower all the stakeholders, particularly the patients, in developing solutions to this dreaded disease. We also published the new research from the lab of Prof Chanda Kulkarni which showed the neuroprotective role of Gabapentin on Aminophylline induced epileptogeneis mouse model apart from articles communicated from the lab of Prof Thakur and Prof Mohankumar. Prof Denis English, the Founding Editor of Stem Cells and Development, adds,' in the lead commentary" the journal can initiate its trek into unanswered questions of past investigators by reprinting portions of the classic work of Karl S Lashley who searched for the 'engram' from 1920 till 1950, never finding the elusive link thought to convert short term memory to one stable, came up with a number of brilliant alternate hypothesis'. The classics section is therefore, attempting to address such issues which have long been forgotten and remained unfunded for advancement of field. Printing the old articles of legendary researchers attempts to bridge this gap.

# World Neuroscience leaders on the Board

This is the first time when so many International leaders have come to join hands under an Indian Journal reflecting the aims set by the Academy. The April issue of 2009 announced a new team of editorial board members that include the best brains and stem cell researchers in Neuro-sciences from around the world, representing almost all major countries. A deliberate attempt was made to include only those names that have genuinely influenced the field. Denis English, the Founding Editor of Stem cells and Development, the Senior Editor of Journal has continued to provide constant guidance with his commentaries alongwith Prof S Prabhakar, the Head of Department of Neurology who is known to have led the indexing of Neurology India. Prof Anand Swaroop from NIH, USA whose leading work in retinal regeneration is well known, continues to play a prominent role as Executive Editor and has provided critical advice of how to seek out important partners. The other Senior Editor is Prof Ante Padjen from International Brain Research Organisation (IBRO). Prof Satyanarayana who is the Editor of Indian Journal of Medical Research, and Prof Gurudutta from Stem Cell Group in Defence Research Development Organisation (DRDO) and Prof Shashi Bala Singh, the Director from DRDO, Leh are the part of editorial team. Rakesh Biswas, a friend, philosopher and Deputy Editor of BMJ Case Reports has been a major support in helping introduce innovations in medical journalism and will play a defining role in the further growth of the journal.

The editorial team is joined by the legendary Colin Masters from Australia who made significant discoveries in the field of Alzhemier's disease and Youdim Moussa from Israel who has also been involved in the discovery of several drugs for Parkinson's disease. Among the other well known scientists include, Prof Mriganka Sur from MIT, Prof Walter Bradley from University of Miami and Prof Tanaka from RIKEN, Japan. Prof Obaid Siddigui, the founder Director of National Centre Biological Sciences (NCBS) and Prof Lakhotia, the Dean of BHU are fellows of Indian National Science Academy (INSA) and have continued to guide on various

matters of the Journal while being on the panel. The new editorial board also included Prof MRS Rao, who was nominated by Prof CNR Rao as the Ombudsman. He is the President of Jawaharlal Nehru Centre for Advanced Scientific Research (JNSCAR), Bangalore. Prof A Surolia who is currently the Director of National Institute of Immunology (NII) remains the scientific advisor. Dr Y.K. Gupta from AIIMS, Prof H H Garcia from Peru and the leading stem cell researcher Prof Peter Andrews from UK became the part of the editorial team. Mr Pavan Duggal, the person who revolutionised the cyberlaws and intellectual property in the country was joined by famous United States Patents Treaty Organisation (USPTO) attorney Michael Coblenz, who together provide constant legal support to the journal which is now being widely recognized as the fastest growing iournal in this subcontinent.

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#### Online submissions

The online submissions for *Annals of Neurosciences* have been implemented through a new portal www.annalsof neurosciences.org. A huge effort to scan, OCR, generate DOIs and reload the old issues into the brand new web site is nearing completion. Annals has partnered with Cross Ref and PHI services for the monumental job of tagging all articles and the accompanying cross references with their DOIs from 2005. This has been a very labour intensive process and some of my lab members and other volunteers are together building this strong foundation for years to come.

#### Indexing

Annals of Neuroscience has been indexed by CAS (Chemical Abstract Service), DOAJ, EBSCO, Index Copernicus and Google Scholar. A new e ISSN no has been obtained. Indexing with PUBMED is an extremely competitive process decided by a 15 member committee which meets to review more than 150 applications 3-4 times a year. The Journal is reviewed for evidence of scientific quality, peer review, ethical standards, disclosure statements, global audience and a promise

for emerging field combined with an International panel. While it is generally believed that Publishers play a significant role in indexing and offer a preexisting International audience to the Journal, the opportunity for board members to interface with policy makers, business houses, society and the media is partly compromised in the process. Journal of Neurosciences or the Indian Journal of Medical *Research* are examples that do not have publishing partners even though their citations have taken decades to build. It is expected that the Journal will acquire indexing and an impact factor in next two years and it is hoped that some decision is reached when Pubmed committee meets at the end of this year. The only other Neuroscience related journal in the country that has powered its way to indexing includes Neurology India and Annals of Indian Academy of *Neurology* whose focus, however, is on clinical Neurology. The recent release of impact factors has seen a significant decline among these

local journals. It is advisable to cite as many articles from the Annals of Neurosciences as is scientifically justifiable so that the goals of enhancing visibility to the journal are realised. More submissions from academy members and other readers will greatly aid the indexing and citations of the Journal.

#### Fund raising activities

Initial seed money came from the family and friends of Editor and Board members who understood the spirit behind the revitalizing of Annals of Neurosciences that they agreed was a national initiative. The Journal has been active on the fund raising activities. It is also proposed to announce neuroscience journalism fellowships to boost these activities. The Editorial team will soon announce these fellowships. The new proposal to enhance the advertising rates and subscription rates have also been introduced. This will enable the Journal to meet the increased costs of production. The members are requested to come forward and participate in these activities and donate liberally for this cause.

#### New Partners

The Journal is leaving no stone unturned in its aggressive pursuit of seeking out new stake holders and patrons in the advancement of the cause for which the Journal has been revitalised. Among the new readers of the Journal are PMO, Secretaries of DBT, CSIR, ICMR, major lobby groups in Business, Academia, Bureaucracy, Law Firms, Social Scientists and Patients such that its growth becomes truly inclusive.

#### Publishers

Indexing is greatly aided with the availability of Publishers but the consensus on seeking out a partner has not been reached yet. Three major publishers have independently contacted the Editor. These include *Bentham Publishers, BMJ* and *Medknow publishers*.

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#### Akshay Anand, Ph.D Editor-in-Chief

References

- Anand A. Science entrepreneurship Challenges and opportunities in India, Journal of Public Administration and Policy Research 2009 ; 1 (1): 1-3.
- Anand A. Journal needs aggressive policy. Editorial, Annals of Neurosciences 2009; 16(1): 1.

# neural stem cell therapy how the hype began

Stem cell therapy has been held as a promising avenue to restore tissues lost to chronic diseases of aging, including those of the brain. However, despite reports using animal models, no therapeutic advance associated with neural stem cells has reached the clinic, since no advance has been reproducible or effective. However, many think that the only obstruction to our ability to cure diseases such as Alzheimer's and Parkinson's result not from failure of stem cell therapy but from regulatory impasse. There was wide and rampant speculation that when this impasse is lifted, cures for chronic diseases of aging shall be immediately available. Many individuals called for an end to the ban on embryonic stem cell research. In large part, this call stems from the failure of adult stem cells to reach the promise stem cell investigators held out a decade ago and from early demonstrations that embryonic stem cells could apparently mend a severed spinal cord. If embryonic stem cells could effect this result, it would be logical to assume that they may be beneficial in chronic diseases of the brain. While stem cell therapeutic advances judged in animal models has now for the most part been attributed to the release of cytokines and growth factors, there is no reason to conclude that stem cells, embryonic or otherwise, restore functional neural tissues or connections of the central nervous system. However, many believe that they do. The questions are why this belief is strongly held, one, and second, do the facts and passions provide any rationale to deliver now that the ban on embryonic stem cell research is thing of the past?

First, we postulate that embryonic stem cell research holds potential problems that transcend religious, ethical or moral principles. Changing the fundamental components of life as we know it may end life as we know it. While science has enjoyed a very liberal scope through the years, certain items perhaps should not be altered by investigation. Nature has a way of ensuring its own survival and the survival of nature was in fact threatened by our exploration of atomic nuclei, an exploration that resulted in the discovery of ways to unleash unimaginable energy that was first used for destruction. While no living being or component thereof is immortal, the fundamental law of nature holds mankind to be immortal, and in this, we survived eminent termination as nature must have known we would and always will. In doing so it allowed us to develop nuclear destructive devices, if only to illustrate their potential to immortalize mankind, an accomplishment Nature shall never allow. But while Nature may well have considered our ability to release the forces of atomic nuclei, and our wisdom in keeping these forces at bay, it is not at all clear that Nature similarly anticipated our drive to understand the basis of life itself would lead to our ability to alter its fundamentals. Embryonic stem cells may well represent an item with which we should not alter; because if we do, we have no idea of the forces we may release or our ability to contain them. Yet we persist, and scientists demand cloning of engineered nuclei of life, an undertaking that could surpass the threat of atomic extinction and to which Nature did not anticipate. Before this research reaches a state that is essentially irreversible, we should contemplate the results, and what we may attain in further studies. Diseases of aging are part and parcel to Nature's grand design. No one lives forever, and no one ever shall, but mankind will unless we put a premature end to our own existence. Stem cells of the embryonic kind fuel concern that we may be approaching that goal, if indeed this is the goal.

This report shall offer two diverse perspectives on the reported success of stem cell therapy for neural reconstitution. I shall provide evidence that no neural reconstruction has been achieved in any system while Dr. Akshay shall provide evidence that reconstruction has been achieved. In addition, this report shall provide a historical perspective of the hype that has driven many to accept the notion that CNS repair can (and has) been achieved with stem cell therapy. The history of the field is unprecedented in Science and has led to dogma prematurely assumed to be correct, while therapy has not been available for patients with neural disorders.

Although the primary goal of medical research has been to alleviate suffering, immortality has never been the espoused objective of either evolutionary biologists or stem cell researchers. Understanding the complexity of life, particularly unmasking of the mechanism of rescue of function effect of stem or progenitor cells remains a challenge that, many believe, will take time, hype (read hope) and multidisciplinary effort to resolve. The hype that has been created in hope of stem cell therapy reminds one of the hype that once existed when the prospects of gene therapy were being debated several decades ago. The era was characterised by a similar overexcitement of physicians who went ahead and carried out an FDA approved clinical trial which led to the death of an 18 year old volunteer, Gelsinger. The whole pack of cards came crashing down, threatening future funding and research in gene therapy. The incident also killed, in a way, not only the hopes that had been kindled by the prospects of gene therapy but also the 400 planned clinical trials at that time. However, it taught us several lessons, one, that clinical trials should be funded and planned with active involvement of basic scientists and not until proof of principle has been reasonably well established. The enormous publicity received by stem cells is partly due to controversies of regulating (or not) stem cell research and partly due to the publicity given to cloning of Dolly. The success of current stem cell trials being carried out today hinges on dominant role of basic scientists. In this context, it is worth contemplating that every jump in technology takes time and incremental advancements before it settles down successfully, for instance it almost took more than a century for an antibiotic like Pencillin to be discovered and enter the market<sup>1</sup> and another half
century for insulin to hit the clinics.<sup>2</sup> While a few may term stem cell therapy hype as dangerous, many counter argue that it is very good for raising the expectations and delivery standards from stem cell investigators. There have been several controversies that marked the launch of antiepileptic drugs,<sup>3</sup> but these could not deter the researchers from abandoning their plans for further advancement. Today, there are half a dozen variants of such drugs available in the market. Similarly, the lack of visible clinical benefit from stem cells should not serve to discourage the scientists. On the contrary, it should catapult them to intensify their efforts further until the incremental advances in the field lead to fulfillment of hopes held by the hype.

The prospect of repairing the damaged brain has provoked excitement, controversy and conflicting scientific claims. The brain was considered unchangeable as postulated by Cajal several decades ago. Altman later showed that neurons can regenerate by H thymidine incorporation studies.<sup>4,5</sup> Many reports have provided interesting leads using disease models where satisfactory functional recovery of cultured neurons has been shown.<sup>6</sup> There have also been several reports demonstrating the functional revival of damaged brain when embryonic stem cells, including neural stem/progenitor cells were implanted in various animal models of neurological disorders. These reports have demonstrated that the stem cells not only repair the damaged portion of the rodent brain but they also promote survival and delay neuronal cell death.<sup>6</sup>

There are populations of proliferating progenitor cells which are now believed to give rise to new neurons in sub ventricular zone (SVZ) of the lateral ventricles<sup>7,8</sup> and in subgranular layer of hippocampus<sup>9,10</sup> raising hopes of curing degenerative diseases. The group of Alvarez-Buyla<sup>11</sup> has shown that GFAP positive astrocytes are the source of neurogenesis in SVZ and sub granular region of hippocampus, the seat of spatial memory. Such advancements are critical in laying the road map for ultimate goal to repair the damaged or degenerate brain. Nakatomi et al even showed that infusion of epidermal growth factor (EGF) and fibroblast growth factor2

(FGF 2) into the lateral ventricle of the rat model of ischemia, in which CA1 neurons are selectively lost, leads to recovery of memory and learning function with concomitant regeneration of pyramidal neurons due to neurogenesis.<sup>12</sup> This has facilitated the discovery of factors that would enable desirable neurogenesis. For example, Gage's group even showed that enriched environment and exercise improves neurogenesis and learning<sup>11,13</sup> lending credence to the hope that environment can greatly influence the rate of neurogenesis. From the time when neurological disorders were left with limited treatment we are entering an era where cellular therapy may finally be able to reverse the disorders of brain. Similarly, there are reports that discuss the functional recovery of animals models when dopamine neurons derived from ES cells were implanted,<sup>14,15</sup> however, a very detailed analysis and further investigations can only lead to mapping of the cues that influence incorporation and differentiation of stem cells. In another development, Harris et al recently showed that intravitreally injected CD 133 progenitor cells from bone marrow can even regenerate retinal pigment epithelium (RPE) cells and improve retinal function, as evaluated by ERG, providing functional recovery of the visual cycle.<sup>16</sup> This is one of the findings that has implications for treatment of age related macular degeneration. One of the challenging tasks confronted with researchers today is the problem of translating the stem cell technology to clinic. As bulk of stem cell translation is happening in the Eastern part of the world, it is important to understand the socio-cultural factors which influence the dimension of scientific output. Most of the countries such as Korea, Japan, Singapore, China or India do not have MD-PhD programs in their Institutes or Universities. Many argue this to be one of the key determinants of stem cell translation to clinic. The lack of scientifically designed trials or absence of double blind placebo controls in such important studies may have consequences that can irreversibly alter the pace of clinical translation. Sandhya Srinivasan argues about the state of stem cell clinical trials in Indian subcontinent, in her article, 'Rogue research in the guise of Stem cell therapy' citing the experience of former Chief Minister, Mr Jogi from Chhatisgarh, who noted 'significant improvement' upon stem cell transplantation after his spinal injury.<sup>17</sup> Even though no conclusive evidence of such therapy was previously available, such small commercial clinics are openly endangering the hope stem cell therapy holds for us today. Even though there has been concerted effort to reconstruct the neurons using stem cell therapy, such unregulated trials such as those happening in one of the top medical institutes such as AIIMS, New Delhi<sup>18</sup> have the potential to create the same fear that gene therapy trial once did several years ago. Maintaining linkages with basic scientists is thus an urgent requirement, no longer a choice, in order to avoid unscientific trials, achieve homogeneity in the quality of stem cells to be implanted, maintaining the correct doses and devising the best route of administration to be followed. Only when these issues are addressed by parallel animal experimentation, the leads can be consolidated by clinical studies. It is being increasingly felt among scientists that there is rampant and sudden urge among the physicians to glorify themselves in the name of providing stem cell therapy to patients even though the studies are only at experimental state. People have suggested several ways of curbing this, one of which is to employ the skilled researchers who are trained to understand the value of a common transplantation SOP, one who understands the value of bench work and the drivers of biotherapeutics. This problem has been well addressed in US, where, despite the ES cell research being under scanner, the scientific community is replete with clinical-scientist entities. There are some who believe that it is the difficulties in intellectual property of stem cells which is actually hindering the pace of clinical translation than the stem cells themselves. Therefore, one can argue that the failure of stem cells to quickly yield desirable clinical end points may not necessarily be a result of failure of stem cells to deliver. Instead, this could be due to the inability to plan the animal studies in a reproducible and meticulous manner coupled with lack of blinding of

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researchers when the experimental

groups are planned. Infact, the generality of need to urgently address such problems in any animal and clinical study can determine the pace of discovery. It is pertinent to note that the lackadaisical approach in translation of neural stem cell therapy is conspicuous when compared to fields such as physics, material science, space science or chemistry where the progress is more visible and rapid. It is possible that a large number of animal models often do not simulate the disease being investigated and extrapolation of results therefore becomes difficult. The appropriate translation dynamics for validating therapies in patients requires rational scaling from rodents-primatehumans, an approach that is abysmally deficient in collaborative effort amongst clinicians and scientists. The regulatory impasse in the use of non human primates coupled with unregulated exploitation of stem cells in the name of patient benefit may not bode well for terminally ill and unsuspecting patients; this has the potential to derail the tremendous impact that the stem cell research is worthy of making.

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#### References

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- 1. Sykes R. From discovery to product Bull World Health Organ. 2001;79(8):780-90.
- 2. Rosenfeld L. Insulin: discovery and controversy Clin Chem. 2002 Dec;48(12):2270-88.
- Sigamani A, Roy AK, Yeragani VK, et al. Hrofile of pharmacotherapy and pharmacoeconomics of epilepsy treatment at a tertiary care hospital. Annals of Neurosciences 2006;13 (4):103-112.
- Altman J: Are neurons formed in the brains of a d u l t m a m m a l s? Science 1962;135:1127–1128.
- Altman J: Proliferation and migration of undifferentiated precursor cells in the rat during postnatal gliogenesis. Exp Neurol 1966;16:263–278.
- Bjorklund A, Lindvall O: Cell replacement therapies for central nervous system disorders. Nature Neurosci. 2000;3:537–544.
- Lois C, Alvarez-Buylla A: Proliferating subventricular zone cells in the adult mammalian forebrain can differentiate into neurons and glia. Proc Natl Acad Sci USA 1993;90:2074–2077.
- Cogliati T and Swaroop A. stem cells and neuronal repair. Annals of Neurosciences 2009; 16(4):143-145.
  - Gueneau G, Privat A, Drouet J, et al. Subgranular zone of the dentate gyrus of young rabbits as a secondary matrix. A high-resolution autoradiographic study. Dev Neurosci. 1982;5:345–358.
- Altman J, Bayer SA: Migration and distribution of two populations of hippocampal granule cell precursors during the perinatal and postnatal

periods. J Comp Neurol. 1990; 301:365–381.

- 11. Van Praag H, Christie BR, Sejnowski TJ, *et al.* Running enhances neurogenesis, learning, and long-term potentiation in mice. Proc Natl Acad Sci USA 1999; 96: 13427–13431.
- 12. Nakatomi H, Kuriu T, Okabe S, et al. Regeneration of hippocampal pyramidal neurons after ischemic brain injury by recruitment of endogenous neural progenitors. Cell 2002;110:429–441.
- Van Praag H, Kempermann G, Gage FH: Running increases cell proliferation and neurogenesis In the adult mouse dentate gyrus. Nat Neurosci 1999; 2:266–267.
- Pal GK, Pal P, Nanda N, et al. Study of interaction of estrogen and dopamine injected into ventromedial hypothalamus on control of obesity in ovariectomized albino rats. Annals of Neurosciences 2007;14(1):8-12.
- Kim JH, Auerbach JM, Rodriguez-Gomez JA, et al. Dopamine neurons derived from embryonic stem cells function in an animal model of Parkinson's disease. Nature 2002;418:50–6.
- Sharma NK, Prabhakar S, Anand A. Age related macular degeneration advances and trends.2009;16(2).
- http://209.85.175.132/search?q= cache:TcUmXK9ZQWEJ:infochangeindi a.org/index2.php%3Foption%3Dcom\_ content%26do\_pdf%3D1%26id%3D2 78+nature+medicine+aiims+stem+c ells&hl=en&ct=clnk&cd=14&gl=in.
- 18. Jayram. Nature 434, 259. doi:10. 1038/434259a; 17 March 2005.

# Advancements in Stem Cell Research – An Indian Perspective

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Stem cell research is a promising frontier in biomedical research and therapeutics that will permanently transform the way medicine is being practised. It has been more than half a decade since India ventured into stem cell research arena in a much extensive scale. Undoubtedly, India possesses the initiative, resources and pragmatism to acquire leadership in this important area of biology. The zeal exuded by the Government of India has led to the prompt identification of stem cells as a niche area requiring intense focus. Its translation in real-time is evidenced by its ever-increasing patronage in the form of grants towards infrastructure development and operational activities. In fact, a dedicated task force has been established under the auspices of Department of Biotechnology (DBT), Government of India to recognize the priority areas and to provide financial support to promote this area.

India is poised to acquire leadership in this area by exploiting both the embryonic and adult stem cells systems since neither alone is likely to meet all therapeutic needs. In fact, a lot of thrust has been given to understanding the basic and clinical biology, which are being pursued at various centres (both government and private alike) within the country. Fortunately the religious concerns especially with respect to embryonic stem cells derivation and usage are relatively non-existent in India. Indeed, the fundamental research on embryonic stem cells that could provide clues about developing understanding of the processes of cell differentiation and dedifferentiation would further enable harnessing of the potential of both embryonic and adult stem cells to their fullest extent. Moreover, since the stem cells from most of the lineages in adult retain astonishing level of plasticity, these could help in exploring their transdifferentiation potential, along with the lineage committed embryonic stem cells derived multipotent stem/progenitors, with a view to having possible application in therapeutic transplantations. Countries like India that possess rapidly growing population can exploit the power of stem

cells in establishing authentic human embryonic stem cell lines as well as pioneering regenerative medicine. Establishment of stem cell lines using surplus IVF human embryos and maintaining those in an undifferentiated state in prolonged cultures is of immense significance for fundamental research on stem cells. This would serve as a great source in order to explore our own intellectual potential. Scientists at NCCS, Pune (Dr. Lenka): NIRRH, Mumbai (Dr. Bhartiya); NCBS (Dr. Panicker) and JNCASR (Dr. Inamdar), Bangalore; NBRC, Gurgaon (Dr. Mani, Dr. Seth); CDFD, Hyderabad (Dr. Khosla), RGCB, Trivandrum (Dr. James) and the private organization like Reliance Life Sciences, Mumbai, among others, are actively involved in embryonic stem cell research from sources of both murine and human origin. Some of the recently published reports on partially/fully characterized human embryonic stem cell lines (Mandal et al., 2006; Lenka and Ramasamy, 2007; Inamdar et al., 2009; Kumar et al., 2009) indicate the progress accomplished in this direction. Moreover, attempts have also been made at NIRRH, Mumbai (Dr. Bhartiya) to establish somatic cell nuclear transfer (SCNT)/ therapeutic cloning in primates as well as in human species. Further characterization of these reprogrammed cells into various lineages as well as developing strategy for the enrichment and purification of lineage specific stem cells would supplement their clinical relevance in cell replacement therapies in treating various degenerating diseases. The recent revolution in the stem cell arena, the establishment of induced pluripotent stem cells has also been initiated by a couple of groups within the country and will bear fruit as institutional support mechanism work in tandem with enhanced outlay for stem cell research.

Keeping pace with the global thrust, scientists in India are also actively engaged in various aspects of tissue specific stem cell research – fetal and adult origins. While work on neural stem cells is a major focus at NBRC (Dr. Mani), NCCS (Dr. Shastry, Dr. Shiras and Dr. Lenka), NCBS (Dr. Panicker), TIFR (Dr. Tule and Dr. Vaidya), PGI (Dr. Anand) and LVPEI (Dr. Kashvap), the group at CCMB studies stem cell quiescence using skeletal muscle cell lines (Dr. Dhawan). Major strides have been made in the hemato-poietic stem cell research by NCCS (Dr. Kale), NII (Dr. Mukhopadhyay) and INMAS (Dr. Gurudatta) among others, in basic biology, maintenance, and signaling cues underlying hematopoiesis. More-over, successful endeavour of NCCS scientists (Dr. Limaye) in devising the technology for efficient cryopreservation of umbilical cord blood and bone marrow derived stem cells has resulted in transferring the know-how to nearby hospitals with a view to venturing into therapeutic exploration. In fact, in NCCS alone a number of groups are already pursuing investigations on stem cells from hematopoietic, neural, cardiovascular and pancreatic origin with active collaboration with clinicians. Efforts are also ongoing in understanding the biology and significance of cancer stem cells at NCCS (Dr. Bapat, Dr. Shiras) and IISc. (Dr. Rangaraian). The future course will be determined by the pace of integration of nanotechnology and biomaterial scaffold for engineering tissues in a 3D platform, that can also boost interdisciplinary research.

Several research institutions and biotech companies have been formed with the mandate on bringing stem cell research outcomes from bench to bedside. Some of the major medical institutions like PGI, Chandigarh; AIIMS, New Delhi; SGPGI, Lucknow; CMC, Vellore; AFMC, Pune, Manipal Hospital, Bangalore; CLRI, Hyderabad have either already initiated or are in the process of venturing into stem cell transplantations using sources like umbilical cord blood and bone marrow in treating neurological, hematological, hepatic and cardiac disorders. LVPEI, Hyderabad and Shankar Netralava, Chennai have successfully carried out limbal stem cell transplantations and restoring vision to many. Among the private companies, Reliance life sciences, Mumbai and Stempeutics, Bangalore are the key players in conducting stem cell



research and clinical transplantations. Stempeutics, which is a wholly owned subsidiary of India's Manipal Education and Medical Group (MEMG), has opened its RM20 Million groundbreaking stem cell research facility in Malaysia, leading the way for such research to be conducted in the South East Asian Nation. Another new venture such as FIRST (Foundation for Innovation for Research in Stem Cells and Therapeutics), is being shortly started in Chandigarh, planning to create a new model of partners that involve people from various disciplines.

Incidentally, India is emerging as a clinical hub for stem cell transplantations and with the new law allowing public-private partnership, would let the scientists at public sector create new spin offs and hold equity in private enterprises, eventually setting the pace in favour of stem cell entrepreneurship. However, the flip side is that, a lot of hype has been created with respect to the stem cells therapeutic implications. Though ethical guidelines are in place, these are probably not as restrictive as in some other countries like USA, Germany etc. The patients and caregivers remain ignorant of the status of stem cell therapeutics and are generally lured by certain private clinics which showcase tempting success stories without long term monitoring practice, providing therapy without any regulatory approvals. In addition, the cost effectiveness of treatment in comparison to similar centres in other developed countries has further vitiated the flourishing medical tourism in the country. A major restructuring of research system within medical institutes can set the pace with which the quality of stem cell transplantation will be delivered. Even though the results of Industry-Academia partnership has been dismal, it is virtually absent in medical institutions where the

real clinical trials are currently taking place. It is hoped that, the new regulation allowing scientists to start their own scientific enterprises will throw up many entrepreneurs from such institutes rekindling the dormant link between Industry and Academia. This will also lead to regulation of unethical transplantation practices prevalent in some pockets in the country.

Stem cell research is indeed a very challenging area from both basic scientific and clinical perspective. On one hand, it is an expensive area of research involving very high cost of consumables, reagents and equipments, where the role of industry is highly desirable, while on the other hand the research training of clinicians is grossly lacking (there is no viable MD-PhD program), a hurdle that is being attempted to be overcome by establishment of translational research centres. Undoubtedly, some of the groups in India who are working in this area are competing at a global level and can perform even better if prompt policy changes are brought out to remedy this problem. Similarly, although funding is not a major limiting factor, the funding mechanisms of providing grants along with institutional support system needs major restructuring to optimally utilize the current facilities and skilled manpower for national growth. In fact, overcoming challenges that are prevalent in the research environment in medical and research institutions will determine the quality of translational research. A major policy shift in cropping new leaders of research for science management within the medical institutions as well as research organizations are indeed needed in India. This will set the path for acquiring global leadership in stem cell research in this subcontinent.

The measure of success will also be

determined by setting standards for the collection, processing and storage of cells intended for clinical use. All cord blood banks would have to be registered with the Drug Controller-General of India (DCGI). The NAC-SCRT (National Apex Committee - Stem Cell Research Therapy) and IC-SCRT (Institutional Committee -Stem Cell Research Therapy) have been constituted as a separate mechanism to address the need for extra vigil and expertise. The National Apex Committee is registering all the stem cell research centers, available stem cell lines in India including the newly developed ones, and ongoing clinical stem cell trials in the country. It will also receive periodic reports from the institutional SCRTs and provide the status of SCRT from time to time. The National Bioethics Committee has prepared the consent for tissue collection for human stem cell research. Thus, the Indian Government is playing a proactive role in guarding research ethics and guality output. The clinician-basic scientist interaction will determine the success of stem cell translation which is steadily coming to fruition with intensive efforts in recent years. Dedicated centres for stem cell research are in the pipeline with multifaceted activities on both basic and applied aspects that could indeed open wider horizon, laving the foundation for a better tomorrow. The scientific community is trying to achieve greater strides in addressing the complex issues in biology that will have implications on medicine of tomorrow. Collective, sincere and dedicated approaches will inevitably help India stand tall in the global stem cell arena.

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## the long and short of it

This editorial is being written at a time when Indian (neuro)science is witnessing a major policy shift in redefining the Indian research. Today we are confronted with a much awaited avatar of Bayh-Dole Act allowing for the transfer of exclusive control over many government funded inventions to universities, Institutions and businesses for the purpose of further development and commercialization. This bold initiative communicated by Ministry of Science and Technology seeks to transcend mere licensing of inventions to third parties to strengthening scientists' claim of holding equity in scientific enterprises and creating spin offs, exempting them from the draconian cluthches of CCS conduct rules. This recent Govt order is meant to ensure the continued involvement of researchers in translating the inventions or innovations, at any stage of development, through investment of their own money. This has been elaborated in the draft that sets the guidelines about creation of scientist based companies thereby permitting researchers to play a defining role in commercialization of knowledge products while being in professional employment. The entire draft has been published at www.dsir.gov.in for the information of its readers. The new law is applicable to all Institutes falling under Ministry of Health and Family welfare, besides other scientific establishments, providing a unique opportunity for medical institutes to mobilize its intellectual resources to generate wealth, an effort never envisioned earlier. Some feel that this is an opportunity to initiate incubation centres in their campuses and mobilise its human resources to industry and recall them back later to establish their own business development offices for generation of research funds. Both these measures have been sanctioned in the government order with the expressed purpose of supporting internal fund generation projects<sup>1</sup>. Such new wealth can be harnessed for rationalization of patient care costs as well as funding more R&D projects within the Institute. The potential of this approach in transforming regional economies (and that of the Institute) by creation of new companies is borne out of the examples set by MIT, IIT, IIM, Stanford and University of Cambridge, many of which are based on biomedical inventions. By promoting science and engineering based enterprises it has not only opened vistas for Institutes to impact society directly but also paved way for those who possess

considerable intellectual portfolios and are ready to seek new frontiers in the field of technology and national wealth creation endeavours<sup>2</sup>. Many view this new regulation as serving to create a distinct reward system for over performers over average workers and may have potential to reverse brain drain. This could serve as a good tool for growing Institutions that are apparently not able to support their own thought leaders for want of stringent service conduct rules. The leadership displayed by IIT entrepreneurship schemes is laudable for others to emulate. Nusrat shafiq argues in her commentary in this issue why there is lackadaisical approach in asking good research questions, makes one think why the Indians who are settled abroad perform better than those who live in this country. Perhaps the right individuals with right questions can now expect to be rewarded from taking risks of asking the right questions and creating spin offs. Supten, on the other hand, argues in his commentary why number of years in service should be a necessary replacement for merit in science. Like developed nations, where excellence is the hallmark of career(read national) advancement, India too needs to experiment with its policies such that many Gokhales are given leadership roles of research organizations, journals and academies. It is therefore not difficult for India to regain its global leadership in the field of Science and Education. It would, therefore, be very interesting to see how the new regulation is shaped in the context of authority (read seniority) patterns identified in Supten's commentary.

Given the impact stem cell research is making in transforming regenerative medicine, this new law can enable researchers to create practical solutions by meeting social challenges and to directly participate in creating and sustaining competitive, self financing and low cost patient care industry for decades to come. This can be conceptualized by mobilising investment of several business houses who might want to set up their centres within the institutes, particularly medical organisations, and fund research in return for commercialisable products. At a time when organisations like CSIR. IIT and IISc have devised mechanisms to open incubation centres, medical institutes in the country have a unique opportunity to make impact in the field of biomedical innovation and not be left behind in the race.

The new law provides opportunities to aggressively establish for itself a corpus of individuals which can generate wealth for it. The new provision allowing mobility of faculty to and fro from industry, can accelerate seamless transfer of knowedge from one organization to other and industry. This regulation can now provide competitive edge to an Institute which is bestowed with faculty with special skills and entrepreneurial drive than those Institutions that don't. Therefore, an early composition of task forces to oversee the establishment of such offices will be the key to consolidation of an early lead in the field that will now become intensely competitive and attractive. Such a set up is bound to stimulate product (or patient) oriented research in anticipation of profits. Many see a dream opportunity for medical Institutes to translate this regulation into establishment of Business Development office comprising people from Knowledge management (such as IP management), informatics, quality control and as venture capitalists.

Young entrepreneurs in scientific journalism too have a new opportunity to combine their enthusiasm, ideas and productivity with advisory role of accomplished scientists so that a new order of thought leadership is created in running journals. Journalism is likely to gain because many may opt to start new journals as a spin off. New ideas of enhancing visibility to journals will include experiments with its design, content, enhanced investments, new breed of publishers, venues and leadership roles<sup>3</sup>. This will eventually lead to new dimension of neuroscience publications in the country. Some will guestion publication ethics, others the national funding mechanisms and policies, some the value of research audit, some the scientific dogmas and yet others the science leaders themselves.

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#### References

- 1. Anand A, Science entrepreneurship: Challenges and Opportunities in India, Journal of Public Administration and Policy Research 2009;1(1): 1-3.
- Das P, Economic liberalisation and R&D and innovation responses of Indian public and private sector industries. Int J Manag Decision Making 2004;5(1): 76-92
- Anand A, Journal needs aggressive policy, Editorial Annals of Neurosciences 2009;16(1):1.

Short Communication

# Science entrepreneurship: Challenges and opportunities in India

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The rise of economy and information technology is fast transforming the intellectual property and technology commercialization in the developing world, particularly in India. absence of awarenesss, strong domestic pressure groups, lack of consortium of IP attorneys and scientists, biotechnology firms and private sponsored research coupled with increase in brain drain have tremendously affected growth of knowledge economy and value creation. With a new patent law of 2005 in place along with new regulation, which will allow Indian scientists to float their own companies, India is poised to overcome most of these challenges. Indeed, recent results show this is the case, reflecting the success India gained in developing computer technology just a few years ago. It is anticipated that this environment shall foster and facilitate new therapeutic approaches to devastating diseases, particularly chronic diseases of aging.

Key words: Wealth creation, research, commercialization, knowledge, economy.

## INTRODUCTION

## Historical overview- philosophical barriers

From 1 AD to 1700 AD, India and China had together commanded respectable share of world's economic assets (Prime and Kulkarni, 2007). In the subsequent years, particularly after the second world war, United States and Europe judiciously utilized the IPR regime as an instrument of economic progress enhancing their wealth by technological breakthroughs which India could not emulate. Representing a sixth of human resources, as fountainhead of 4 major religions and the largest democracy, India possesses rich ancient knowledge besides access to modern technology. It has given the number system to the world and several discoveries in fields of mathematics, physics and biology besides producing several thinkers, philosophers and noble laureates (Gup-ta, 1983). India has, however not optimally tapped the immense potential of its intellectual pool for enhancing its wealth. In this article some of these causes have been traced in order to understand this impasse. These challenges transcend mere access to or acquisition of technology to cultural, institutional and philosophical barriers in adoption of IPR regime and its commercialization as foreseen by WTO or TRIPS. Indians have always attached a lot of sanctity to knowledge and the deliverer

of knowledge, the guru or teacher and the Goddess of knowledge, Sarswati as much as Lakshmi, the Goddess of wealth (Ankrl, 2000). Some thinkers believe that the genesis of the problem of dissociation of wealth creation efforts from knowledge lies in the known relationship problems between Sarswati and Lakshmi. The idea of science entrepreneurship thus never visited the political thinkers, policy makers or the academicians until very recently. Majority of the research in India has thus continued to be supported by only public funds which owes its origin to existence of Gurukuls (free residential schools) because of which the licensing and protection of patents remained under bureaucratic control. Absence of strong domestic pressure groups and private sponsored research has simultaneously contributed to lack of interest and aware-ness about such issues. Coupled with an all-pervasive philosophy of Vishwa Kutumbukum (world is a single big village) the scientific patriotism could never acquire pro-minence among Indian scientists making it difficult for them to link their productivity with national benefit. Even the great Indian scientists like JC Bose or CV Raman re-frained from accepting financial gain from their research which served as a bad precedent for others scientists.

#### Socio political factors

Politics in multicultural, multicaste Indian democratic society has further eclipsed the vast potential of talent by promotion of caste based reservations in professional education. http://www.frontlineonnet.com/fl1420/1420099. 0.htm). Although there are benefits of reservation from the point of view of providing opportunites for disadvantaged sections of society the idea of addressing social inequality by reserving seats for technical jobs in present form is not beyond debate. There is a recent ruling by supreme court providing reservation immunity to IITs (Indian Institutes of Technology) and top some medical institutes. There are other factors that determine funding in medical research which are dependent on relative spending in other national priority areas. For example, with rise of terrorism, India is constrained to earmark a big share of its resources in defence and for fighting terrorism. This has been continuing for past 2 decades because of the R and D expenditure has never crossed 0.84% (Ankrl, 2000). As a result, many young and creative scientists from developing countries prefer to migrate to developed countries. When these scientists decide to return home, their right to claim the IP assets they created abroad is either lost or difficult to pursue. Therefore, the conesquent opportunity of revenue generation is also lost. Thus, there is need for global law that can address the issues of migratory population of scientists which is routine. However, only recently India has greatly increased investments in R and D which is evident by establishments of several new institutes in the country such as IISER, IITs and one Stem Cell Centre in Bangalore.

## Academic challenges

An important challenge confronting the biomedical scientists is the lack of understanding of the linkages between investment in research and rationalization of medical treatment costs that has never been adequately highlightted by science and health managers. As a result very few, if any, medical institute have a well established patent office, a business development office or an office of integrity to address issues that emerge from biomedical innovations. Such institutional and faculty support systems are important to complement the enhanced funding in R and D. One way of addressing this issue could create positions of directors of research within medical institutes who possess deeper understanding of drivers of research translation. Such a model exists e.g., in LV Prasad eye institute, Hyderabad, one of the leaders in vision research and clinical translation. Very recently the national institute of immunology, New Delhi has initiated a translational research institute. Such models have led to excellent integration of clinical and basic research efforts enabling the stem cell technology to become a reality. Such efforts can enable the stem cell technology translation at affordable costs. In order to optimize scientific productivity the existing authority patterns can be slowly replaced by teamsmanship in such organisations such that the performance and satisfaction levels of human resources are maximized for utilization in innovative projects for societal benefit. In this regard, India boasts of a far more liberal policy in stem cell research when compared to USA and hence there is an opportunity of rapidly acquiring leadership in this area. There is no philosophical barrier that restrains the stupendous advancement the country is making in stem cell technology but in order to acquire global leadership in this area the above mentioned socio-political, human resources and policy issues need adequate attention.

## Controversies and promises

Human resource is one of the biggest problems in contemporary academics. Without a distinction between under and over performers the success for a innovation system to deliver is very little. The scientists are evaluated by the years of service than contribution alone, much like administrative staff. The recent proposal in India to allow scientists to share part of the patent money is a welcome breather in this direction. In this regard, Panjab University took the lead by announcing extra monetary reward for those publishing in high impact factor journals, highlighting the urgency to reward those who put that extra effort in academics. Seniority is another criteria often conveniently accepted as a good replacement for merit in Indian environment. The young faculty involved has to move up from sloganeering to real liberation, by involving them in scientific decision making processes such as task forces that decide funding of research projects, editorial boards of journals that decide acceptance or rejection of new research and inducting them into national academies or Institute bodies. If the bright and meritorious faculty is able to assert themselves in the academic platforms, the innovative systems will become healthy.

The advent of IPR regime and advancement of science has coincided with the entry of national leaders such as ex president scientist Dr Abdul Kalam and economist prime minister Dr Manmohan Singh. As the government conduct rules that do not allow holding of 2 simulta-neous jobs, forming of spin off company from new research until recently has been an impossible task. A mechanism of encouraging in-service scientists to form a company either by taking sabbatical leave or by providing consultancy services while working in these government institutions can change the landscape of innovative efficiency. Although CSIR and IITs have taken lead in these sectors, the medical institutes have been left far behind, ironically it is in such institutes where the stem cell technology has to flow from experimental hands of basic scientists to those of medical scientists including surgeons and finally to private sector. It is here where the need for technology development can play a leading role such that the patients are not left to bear the financial burden of this futuristic treatment. Who will ensure that the technology is passed into private sector properly so that the patients are ethically served and health industry thrives? There are some private centres that have come up which either bank cord blood or provide putative cell replacement therapy and majority of them are devoid of scientist-clincian teams that lack adequate expertise in the field which could pose a threat to human health. A recent news item reported the government proposal, which would allow inservice government scientists to hold equity in a companies directed by them, much like the existing system in west. However, till now no further action has been taken on it. Such bold initiatives hold promises for supporting the new generation of scientists who are replete with ideas and entrepreneurship.

There are also complex global issues of intellectual property such as conception and reduction to practice. authorship and inventorship, plagiarism and protection, debate on live material etc that need to be revisited in the current patent law as this directly affects science entrepreneurship projects. A colloquium of lawyers, scientists, healthcare personnel and policy makers is a requirement that can strengthen the current innovation policy. An organised effort could attract the average participation of scientists in IP policy, its regulation, enforcement and eventual commercialization of research products. This can happen with the involvement of national research development council (NRDC) or technology development board (TDB) or with the recently initiated partnerships between department of biotechnology and private companies (BIPP and SIBRI programs) who are trying to create awareness about these activities. The goverment's policy to promote stem cell research in the manner that ensures safety and efficacy of stem cells is likely to facilitate the unparalleled growth of health industry, results of which are starting to make headlines in the world. Again, the absence of organized offices to oversee such efforts without involvement of basic scientists can derail the entire process, much like well advertised and hurried gene therapy trials in US that led to death of a boy after which the gene therapy trials took a never to return plunge. The situation at the medical institutes is particularly alarming where there is a need for integration of health and science policy for potential research. In medical Institutes the plea serve patients care is often justified as an excuse for neglecting the importance of research and innovation. As a result, the opportunity of working with a huge patient population, particularly the epidemiological aspects, is lost, often at the cost of separating clinical practice from research. The introduction of MD-PhD program, like the one initiated by NCBS, Bangalore can suitably resolve this major problem. Many people also believe that lack of accountability is the heart of inefficiency of scientists and doctors alike. It is also pertinent to review the permanency of government jobs and enhance accountability through regular science and health record audits.

#### Conclusions

It is imperative to make the academic institutes financially autonomous by allowing them to generate and survive on their own funds, this will automatically lead to scientific output, rapid generation needs to be studied by the Indian polity of intellectual property and translational research which can be used for societal benefit. However, will this work out in a country like India with poverty levels to the tune of 48% needs to be evaluated carefully by Indian polity. The institutes will be able to share its profits with the faculty that helped it to become financially independent, as a result the merit will supercede seniority spontaneously and only the meritorious faculty will be able to lead such institutions and the respective departments. The rapid advancements in the area of stem cell research has the potential to make india as an international capital of stem cell banking and therapy, as also highlighted in the recent (2008) editorial by Prof Denis English, founding editor of stem cell and development. If equally rapid policy changes are not implemented, the huge world health care market will be lost forever directly affecting the cost of treatment for poor patients.

#### REFERENCES

- Ankerl G (2000). Coexisting Contemporary Civilizations: Arabo-Mulsim, Bharati, Chinese, and Western. Geneva: Inu Press
- Das P (2004). Economic liberalisation and R&D and innovation responses of Indian public and private sector industries. Int. J. Manag. Decision Making 5(1): 76-92.
- Frontline, (1997) A Continuing Social Outrage', October 4 to 17, http://www.frontlineonnet.com/fl1420/14200990.htm
- Gupta RC (1983). Spread and triumph of Indian numerals. Indian J. Hist. Sci. 18(1): 23-38.
- Prime PB, Kulkarni KG (2007). Economic Development in India and China: New Perspectives on Progress and Change. New Delhi
- Pandit SS (1975). A critical study of the contribution of the Arya Samaj of Indian education, Ph.D. Edu., MSU 1974-2

# Editorial

#### Journal needs aggressive policy

1

I am honored to take over the Editorship of Annals of Neurosciences (ANS) for which I thank the Academy. I have held hectic consultations in order to implement ambitious plans that will enhance its quality, readership and to create a new model for communicating research results, commentaries and reviews. This will be done by expanding its sections such that there is multidimensional flow of scientific information. India, until recently, was riding a wave of economic prosperity and suddenly the scientific output has jumped to a new level never seen before. This could be partly due to enhanced R&D outlay by Indian govt and partly due to the returns from Biotechnology ventures. However, the growth of Indian journals or their citations has not matched those of International journals. Many argue that it is the reluctance of leading Indian scientists to communicate their results to Indian journals that is the cause of low impact factor of our journals, others believe that these journals lack professional competitiveness and business acumen. Prof Lakhotia ran a commentary in Current Science arguing that majority of leading Indian scientists communicate those articles to Indian journals that have been either been rejected from 'International journals' or they themselves view as 'second grade articles'. In contrast, the Chinese, Japanese and several other countries have built their own research around indigenous journals whose impact factors are constantly growing and they take pride in publishing in such journals. In a personal communication with Prof Siddiqui, the founding Director of NCBS,

Bangalore it became clear that quality should not be compromised at any cost even if it involves reducing the issues. Although there is no immediate plan to do this, I wish to announce the new focus of ANS to be on Stem Cell research and Development with commitment to address regulatory issues, and highlight new ideas and controversies, both from bench and clinic. In the subsequent issues we will strive to challenge concepts long established and revisit the aspects long forgotten. We will also attempt to create a new order of thought leadership by introducing a section devoted to 'People and views' that may include biographies of accomplished scientists. There is also a proposal to include patient's views and their version of disease pathology, health economics and experience. This is intended to bridge the chasm between those who run the labs and those for whom the research is intended. We will be publishing the original articles, inviting reviews from successful scientists and clinical researchers, carry reprints of classics, book reviews and a section devoted to graduate students, a need that was visibly felt at the IAN meeting in Kochi. We are also planning to introduce another section on Molecular shots where high quality experimental pictures which will be published as a prelude for papers to follow. Indian and world policy in neuroscience needs special attention and keeping that in mind we plan to invite policy briefs that engage researchers in bringing policy change. With the tremendous spurt of research communications from this region, coupled with an equally fast growth of IT in today's world, the journal is set to enhance the citation of its articles at a pace never witnessed before. This issue features reprints from original manuscripts of Rene Descartes a famous scientist and philosopher, who defied skepticism and paved way for deductive science that we see today. Special permission has been obtained for this.

I have begun deliberations for the constitution of a new Editorial board that will facilitate capacity building, highlight innovative research and create new systems to work in a team such that the journal becomes a true beacon of scientific expression and achieves an impact factor that it deserves. I will announce the brand new team of board members in the next issue. These members will share Journal's short term goal to generate competitive Editorial policies, participate in periodic board meetings, put up new mechanisms for peer review and acceptance of manuscripts. An independent portal linked to IAN web page coupled with reallocation of portfolios and increasing readership of the journal are among some of the other priorities. The long term goal of the journal would be to become the most cited journal in India and Asia. We would be shortly announcing awards for best reviewers and best contribution to journal clubs to encourage young scientists. This would be based on the decision of the committee that would be shortly formed. I solicit your support and advice in raising this journal to new heights.

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