



ABOUT

# HEALTH POLICY INITIATIVE

Indian Council for Research on International Economic Relations

# About ICRIER

Established in August 1981, the Indian Council for Research on International Economic Relations (ICRIER) is an autonomous, policy-oriented, not-for-profit, economic policy think tank. ICRIER's main focus is to enhance the knowledge content of policy making by undertaking analytical research that is targeted at informing India's policy makers and also at improving the interface with the global economy.

ICRIER's Board of Governors include leading academicians, policymakers, and representatives from the private sector. Dr. Isher Ahluwalia is ICRIER's chairperson. Dr. Rajat Kathuria is Director and Chief Executive.

ICRIER conducts thematic research in the following eight thrust areas:

- Macro Management, Financial Liberalisation and Regulation
- Global Competitiveness of Agriculture, Manufacturing and Services
- Multilateral Trade Negotiations and FTAs
- Urban Transition and Challenges
- Climate Change and Sustainable Development
- Physical Infrastructure, including Telecom, Transport and Energy
- Asian Economic Integration with Focus on South Asia
- Entrepreneurship and Skill Development

To effectively disseminate research findings, ICRIER organises workshops, seminars and conferences to bring together academicians, policymakers, representatives from industry and media to create a more informed understanding on issues of major policy interest. ICRIER routinely invites distinguished scholars and policymakers from around the world to deliver public lectures and give seminars on economic themes of interest to contemporary India.



*On the dais:* Dr Manmohan Singh, Former Prime Minister of India; Dr Raghuram Rajan, 23rd Governor of Reserve Bank of India; Dr D Subbarao, 22nd Governor of Reserve Bank of India; Dr Isher Judge Ahluwalia, Chairperson, ICRIER; Mr T N Ninan, Chairman & Editorial Director, Business Standard; Mr Manzar Khan, Former Managing Director, Oxford University Press, India office.



Dr S Eswara Reddy, Joint Drugs Controller (India); Dr Hemant Koshia, Commissioner, Food & Drug Control Administration, Gujarat; Mr Kenneth C Frazier, Chairman of Board and CEO, Merck & Co.; Dr Kiran Mazumdar Shaw, Chairman & Managing Director, Biocon Limited; Dr Y K Gupta, Professor & Head, Department of Pharmacology, AIIMS; Dr Samir Brahmachari, Former Director General, CSIR; Dr Ratna Devi, CEO, DakshamA Health; Dr Rajat Kathuria, Director & CE, ICRIER; Dr Ali Mehdi, Project Leader, Health Policy Initiative, ICRIER.

# Health Policy Initiative (HPI)

India's growth and development have been seriously hampered, *inter alia*, by efficiency and equity deficits in its health sector. Such deficits are poised to become more pronounced with the growing burden of chronic diseases in the country. Already, 21 percent (3.4 million) of global premature deaths due to NCDs happen in India, the highest in the world. A country with global aspirations cannot afford the loss of human life at such a scale, not to talk of the associated economic costs for households and the country at large. A 2 percent annual reduction in deaths due to NCDs between 2005 and 2015 would have not only led to substantial gains in its labor supply, but saved India 15 billion dollars.

The Health Policy Initiative aims to analyze some of the critical challenges in India's health sector, and likewise develop actionable policy recommendations for health sector reform based on best practices from around the world. HPI has started out with two research programs - viz. the Research Program on Drug Regulatory Reforms in India and Research Program on Tackling Chronic Diseases in India - but would expand to other areas of concern for health policymaking in the country in the near future.

In our research as well as in consultations and dissemination, we adopt a multi-stakeholder approach, facilitating direct stakeholder engagement and consensus-building on major issues of health policy. Based on stakeholder engagement and our cutting-edge policy analysis, we develop and disseminate our policy recommendations for health sector reforms in India.

For more information on HPI and the kind of work we have done till now, kindly visit [icrier-health.org](http://icrier-health.org).

For potential research themes and collaborations, or general suggestions, kindly contact:

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# Drug Regulatory Reforms in India

Indian households accounted for nearly 71 percent of total health expenditure in the country, with close to half of their out-of-pocket health expenditure going into drugs and medicines. Consumers cannot ascertain the quality, safety and efficacy of drugs – especially in developing countries like India, with low levels of health literacy – hence the criticality of regulation in the case of medicines. How can we strengthen and raise the standards of drug regulation in the country, while leveraging the potential of the pharmaceutical industry to address India's evolving disease burden as well as continue to contribute to its growth, more so than it has been? Combining scientific and economic expertise, these are some of the policy issues that this research program seeks to address.

## COMPLETED RESEARCH (2014-15)

### Administrative structure and functions of drug regulatory authorities in India

ICRIER Working Paper 309

### Drug quality and safety issues in India

ICRIER Working Paper 310

## ONGOING RESEARCH (2015-16)

### Harmonization of drug registration procedures – An impact assessment for India

Divergences in national regulatory frameworks have the potential to impose major transaction costs for both regulators and industry, and subsequently pose a challenge for public health. Such concern has provided impetus to international cooperation and harmonization of regulatory standards through initiatives at regional and international levels. India is not part of any ongoing harmonization

initiative. Given that Indian pharmaceutical industry is well-integrated into the global value-chain, and with rapidly changing disease profile in the country needing newer and better treatment options, Indian policymakers need to address the issue of harmonization on a priority basis. This paper tries to explore some of the options for the consideration of Indian policymakers.

### Challenges and prospects for clinical trials in India

Clinical trials are critical for drug development process as they help establish safety and efficacy of new drugs. India has had favorable conditions for conducting clinical research and drug development – a large and diverse patient pool (trial subjects), qualified scientists (investigators), medical institutions (sites), etc. Yet, an unfavorable ecosystem and public perception have undermined their potential – only 19 trials were approved in 2013, a drop of roughly 93 percent from 2012 (262 trials), and a fraction of its peak of 500 in 2010. This paper will look at three key aspects of CTs – ethical, procedural and uncertainty embodied in the current regulations – and develop actionable recommendations for policy reform in the Indian context.



L-R: Dr G N Singh, Drugs Controller General of India; Late Dr Ranjit Roy Chaudhury, Chairman, Chaudhury Expert Committee to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs; Dr Shankar Acharya, Honorary Professor, ICRIER & Former Chief Economic Advisor, Government of India; Dr Kathleen Holloway, Regional Advisor Essential Drugs and Other Medicines, World Health Organization, SEARO office.

# Tackling Chronic Diseases in India

As people age – and as countries progress on the scale of epidemiological and economic transitions – the causes of morbidity and mortality become predominantly chronic in nature. The problem of chronic diseases is much more severe in low and middle countries (LMICs) vis-à-vis high income countries – not only are 74 percent of chronic disease-related deaths concentrated in LMICs, most of these deaths are happening at premature levels (under 70 years), which is the most problematic feature. And, given that their at-risk populations are also substantial vis-à-vis developed countries, the enormous burden of chronic disease-related morbidity, productivity and economic losses too in LMICs is anybody's guess. In India, in 2012, 59 percent of premature deaths happened due to chronic diseases, while 27 and 15 percent were due to acute diseases and injuries respectively. The burden of chronic diseases is only going to increase in the future, with more fatal consequences for India's poor and middle class. This research program aims to draw the attention of both national and state policymakers to this critical area, and provide them with evidence and analysis based on our research in developed as well as developing contexts. Given the promise and potential of prevention based on surveillance in developing countries like India, we started out our research under this program with the following themes and shall be picking up others as we go ahead.

## ONGOING RESEARCH (2015-16)

### Prevention of chronic diseases – Reorienting primary health systems in India

In India, 66 percent of all deaths are premature (under the age of 70 years). While the burden of premature mortality has shifted from child (0-5 years) to adult (30-69 years) level over the years – there are three times more deaths happening at the lat-



Distinguished national and international participants at one of our consultative workshops on chronic diseases. The inaugural address was delivered by Prof David Bloom, Clarence James Gamble Professor of Economics and Demography, Department of Global Health and Population, Harvard School of Public Health.

ter vis-à-vis the former level – primary health systems continue to focus almost exclusively on child mortality. They need to make a health system transition and get engaged in the prevention of risk factors, morbidity and mortality related to chronic diseases – the biggest determinant of adult mortality – together with their original focus on child mortality. This paper analyzes some of the major challenges in terms of governance, manpower and financing that such a transition will be faced with, and offers a number of actionable policy recommendations to tackle such challenges.

### Surveillance of chronic diseases – Risk factors, morbidities and mortality (RMM)

Robust surveillance mechanisms for chronic disease RMM can go a long way in their prevention. Nevertheless, this has not received adequate attention among policymakers in India, and the country's draft National Health Policy 2015 does not even mention it. This paper presents the status, scope and challenges for strengthening surveillance of chronic disease RMM in India, drawing upon the surveillance experience of selected states and countries to develop policy recommendations.

# Some Publications

**Health of the Nation: India Health Report 2018 (forthcoming)**

**Impact of preventive health care on Indian industry and economy**

Alka Chadha, Ali Mehdi, Garima Malik (ICRIER WP 198, September 2007)

**The role of information technology in designs of healthcare trade**

Ajeet Mathur (ICRIER WP 111, September 2003)

**Prevention and control of non-communicable diseases: Status and strategies**

K Srinath Reddy (ICRIER WP 104, July 2003)

**India Health Report**

Rajiv Misra, Rachel Chatterjee, Sujatha Rao (Oxford University Press, January 2003)

**Health insurance for the informal sector: Problems and prospects**

Anil Gumber (ICRIER WP 90, November 2002)

**Trade in health services**

Rupa Chanda (ICRIER WP 70, November, 2001)

**Trade barriers and prices of essential health-sector inputs**

David Woodward (ICRIER WP 73, June 2001)

**Consumption and trade in off-patented medicines**

Harvey E Bale (ICRIER WP 65, May 2001)

**Differentiated pricing of patented products**

John Barton (ICRIER WP 63, November 2001)



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