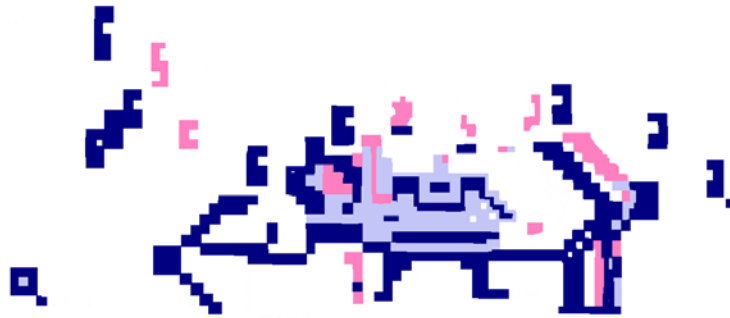


National Health Research Policy



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Preface

Why has a need of a National Health Research Policy arisen now ?

Though history of health research in India goes beyond 1911, when the Indian Research Fund Association the precursor of Indian Council of Medical Research (ICMR) was established, the country did not have a policy laying down the principles to guide decision making until the ICMR formulated a Health Research Policy in 2007.

It is being increasingly realized that better health is not only a consequence of economic development, but also a critical input and a means to achieve it. The discovery, development and refinement of cost-effective interventions can drastically improve the landscape of disease control and health of Indians. Better use of existing health interventions is critical in improving access to these tools and must be given high priority. Equally important is to simultaneously invest in the development of new, improved and equitably and affordable interventions.

There are many players in health research, the public and private sector, autonomous organization and NGOs, bilateral and multi-national agencies. The players in health research are increasing and so is the funding. Better coordination would be the key to judicious use of resources. The other policies enunciated by the Government of India (Population Policy 2000, Health Policy 2002, Science & Technology Policy, 2003) have equivocally stressed the importance of health research to improve health of the nation.

In 2007 the Government of India created a new Department of Health Research within the Ministry of Health and Family Welfare. This was a clear signal that research would play a crucial role in shaping health policies and programmes. Embedded in the charter of business of the new Department was the formulation of a National Health Research Policy. Accordingly, a Committee of Experts reviewed the situation, and its sub-committee drafted this National Health Research Policy. The policy is expected to serve as a beacon to guide health research in India which should contribute towards attainment of better health for all Indians.

The draft Policy was widely circulated and was put on the Council's website for a wider readership for comments and suggestions. 'Open house' were organized in the four metros (Chennai, Kolkata, New Delhi, and Mumbai). It brought together a wide variety of stakeholders spanning across academia, research organizations, private sector, non-government organizations and civil societies, industry, philanthropic organizations, bilateral international agencies, UN bodies (WHO, UNICEF), various Ministries and Departments in the Central and State Government, representative of media (print and electronic). The enthusiastic and spirited discussions provided valuable insight into the expectations of the various stakeholders from the National Health Research Policy. Those who could not participate in the discussions sent in their comments and suggestions through e-mail. The final version has been redrafted and incorporates their aspirations and expectations.

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We thank all who participated in ‘open house’ discussions in Chennai, Kolkata, Mumbai and New Delhi and provided valuable suggestions. We are also grateful to those who read the draft and provided comments electronically. It is upon these critiques, ideas and insights that this Policy has evolved. Thank you.

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Introduction

Unlike medical research, health research is comparatively a new concept. It goes beyond illness to include the research into the various determinants of illness as well as health. Health research, therefore, is systematic generation of knowledge that can be used to promote, restore, maintain and/or protect health of individuals and populations.

The establishment of a Department of Health Research (DHR) in the Ministry of Health is recognition by the GOI of the key role that health research should play in the nation. This decision was preceded by the Report of India's National Commission on Macroeconomics and Health (NCMH) which builds a strong case for investing in indigenous research and encouraging Indian companies and universities in partnership to engage in R&D for drugs, medical devices and vaccines relevant to the needs of India's poor. For developing a culture for research, the Report suggests that the Government should initiate steps to de-bureaucratize procedures, introduce greater transparency, provide incentives and adequate flexibilities to enable engaging and retaining the best minds to undertake research - both in public and private universities and research institutions.

The weakness of the publicly funded health structures and the research infrastructure is a key limiting factor in realizing the full benefits of this commitment to research. The fact that the almost 300 medical colleges in the country are not contributing of their best to health research is highlighted by the fact that in 2007, 96% of the research publications in India emanated from 9 medical colleges. Much of this published research is not on priority health concerns and the translational of key research findings into policy which could improve the health of the people is very limited and needs to be enhanced. Epidemiological know-how, surveillance technology and diagnostic services which are essential for determining health priorities are very poorly developed. With the launch of the National Rural Health Mission (NRHM) and the proposed National Urban Health Mission (NUHM) the enhancement of the above described infrastructure to provide the evidence base for policy and programme becomes a critical issue. There is also a compelling need to build multidisciplinary research blending physical, medical and social sciences. Besides, there is also an equal urgency to establish regulations, strict ethical norms and transparency, standardize methodology and international standards of research. Such capacity is necessary for undertaking operational research as also large-scale evaluation of diagnostics and trials of drugs, devices of both modern and traditional systems of medicine.

It is in this context that the DHR has formulated a National Health Research Policy. In India, while most of the agencies funding research have plans in general linked to the National 5-year Plans, a coordinated national health research policy which could guide the planning and implementation is not yet in

place. The increasing international collaborative research in priority areas of national health also necessitates a clearly spelt out policy to ensure that the contributions of our international partners can enhance the ability of the partnership to improve national health. Some of the conflicts and failures of Indian health research can be attributed to the absence of such an overarching policy.

Health is also now recognised as a fundamental issue in National Development and a factor that promotes equity. A clearly defined Health Research Policy with well defined vision, mission, strategy and deliverables therefore is the basis for maximising the return on investment in this important field. It is imperative that such a policy will give special attention to the health problems of socially underprivileged groups (tribes, women, other marginalized groups) and difficult to access geographical areas.

Vision of National Health Research Policy

To maximize the returns on investments in health research through creation of a health research system to prioritize, coordinate, facilitate conduct of effective and ethical health research and its translation into products, policies and programmes aimed at improving health especially of the vulnerable populations.

Objectives of the National Health Research Policy

The broad objectives of the National Health Research Policy are:

- i. Identify priorities for effective and ethical health research to enable the achievement of the objectives of NHP 2002, NRHM, Bharat Nirman and National Food security Act as well as global commitments such as MDG and IHR, ensuring that the results of health research are translated into action
- ii. Foster inter-sectoral coordination in health research including all departments within the Government, Private Sector and the Academia to promote innovation and ensure effective translation to encourage/accelerate indigenous production of diagnostics, vaccines, therapeutics, medical devices etc..
- iii. Focus on the marginalized, the vulnerable and the disadvantaged sections of society.
- iv. Strengthen national networks between research institutes, academia and service institutes, and encourage PPP
- v. Put in place strategies and mechanisms for assessing the cost-effectiveness and cost benefits of interventions for health.
- vi. Develop and manage human resources and infrastructure for health research and ensure that international collaborative research contributes to national health.

Prescription

1. Create a National Health Research System
2. Establish a National Health Research Management Forum
3. Operationalize a 10-point action programme

National Health Research System (NHRS)

In order to achieve intersectoral coordination and to make national priorities for health research a new architecture of national health research system is envisaged. Health research system is a concept that integrates and coordinates the objectives, structures, stakeholders, processes, cultures and outcomes of health research towards development of equity in health and in national health system. It is a system for planning, coordinating, monitoring and managing health research resources and activities, and for promoting research for effective and equitable national health development

Health Research in the country would be developed into a National Health Research System (NHRS) wherein all research agencies, cutting across Ministries and sectors identify priority areas of research and coordinate with each other to avoid duplication, fragmentation, redundancy and gaps in knowledge, in order to enable the results of research to transform health as a major driving force for development.

Goals of the NHRS

- To generate and communicate knowledge that helps to form the national health plan and guides its implementation, and thus contribute, directly or indirectly, to equitable health development in the country;
- To adapt and apply knowledge generated elsewhere to national health development; and
- To contribute to the global knowledge base on issues relevant to the country

Underlying values of NHRS

The NHRS can only be viable if there are strong underlying values which recognize that health research is an investment which is equitable, based on ethics, owned by the people and leads to development of the Nation. Some of these values are:

Health Research as an investment: Health Research should be considered as a necessary investment for health as well as overall development. Its value as an investment for a healthier population and as a cost- beneficial entity is recognised and acknowledged.

Equity: A commitment to addressing the problems of the vulnerable segments of the population, in order that the benefits of research are accessible to them.

Ethics: A commitment to the ethical practice of health research. The current guidelines will be periodically reviewed and given the force of law.

Self-reliance: Self-reliance in financing, human resource development and upgradation of infrastructure and the sovereign right to determine priorities and set out strategies.

Ownership: All stakeholders in the research process will have the right to participate in and have access to the outcomes of the research. These rights of individual citizens to be aware of and participate in the fruits of research shall be protected.

Solidarity: A spirit of solidarity will be promoted among all the stakeholders in the Indian Health Research System

Development of a Research Culture: It is essential to inculcate a research culture among all concerned with the health sector, in order that the value of research and of researchers is recognised, and a supportive environment for research is created at all levels.

Intersectorality: The essentiality of intersectoral cooperation in health and development will be recognised, and made more effective and meaningful.

Partnerships: Partnerships within the country, and outside would be essential to derive the maximum possible benefit from research endeavours. While strengthening and expanding partnerships the sovereign rights of the country will be protected.

Originality : Focus will be on original thinking so as to become a society of original thinkers and innovators. This will both ensure affordable tools/ products for our population as well as globally competitive and respect in the international arena.

Accountability: Researchers, managers, policy makers and decision-makers will be accountable. The criteria for accountability will not only relate to monetary matters, but also include the translation of research into action.

Functions of NHRS

The National Health Research System would be responsible for:

1. Developing National Health Research Plan

The DHR is responsible for the National Health Research Plan for a National Plan aligned with the Five Year Plans of GOI and its implementation and monitoring.

2. Set priorities

A Priority Research Agenda will be developed in tune with the National Programmes, and relevant to national and local needs, based on the following principles:

a. Responsiveness

Current and emerging issues such as Demographic and Epidemiologic Transition, emerging scientific developments such as Modern Biotechnology (Genomics, Human Genetics, New Drug Development, Stem Cell research), Health system research, Health Economics, Behavioural and social issues, Emerging and re-emerging infections, etc. and the priorities of the National Health plan will guide the Research Agenda.

b. Integration

The integration of the National Research Plan with the priorities and aspiration of society is essential for the ready utilisation of the results of research. The linkages of the health system with communities, District and State Governments and the Central government is essential for developing the data bases necessary for research and service priority setting and decision making. The generation of this data shall be a priority.

c. Multidisciplinarity and Linkages

Health Research, in addition to the field of Health, intersectorally encompasses Education, Environment, Ecology, Social and Behavioural Sciences, Population, Agriculture, Trade, Commerce, in addition to the physical, chemical, biological and mathematical sciences. This multidisciplinarity will be reflected in the national health research plan.

d. Social and Behavioural Sciences and Health Economics

In order to make meaningful health policies, plans and programs and to make medical technology useful and accessible to the community, it is essential to understand the community's perception of health problems, health services and health care providers. Social and Behavioural sciences and Health Economics are integral to health research and will be actively fostered.

e. Focus on vulnerable and disadvantaged populations

Equity in services and development shall be the cardinal principle under riding the Health Research System. There shall be a special emphasis on vulnerable groups like scheduled castes, tribal populations, unorganized labour, women, children, adolescents, North East and the geriatric populations who remain in the periphery of society and the larger health sector. Data on expenditure on health on these sectors, problems on delivery of health care and the potential impact of innovations in public sector financing / resource generation such as user fees, and the economic burden of disease in vulnerable groups and its impact on national development are key issues.

3. Engage with Private Sector

The private sector, pharmaceutical industry, biotechnology and biomedical technology oriented Industries, private educational institutions, hospitals and nursing homes, research foundations and institutions, private practitioners, NGO's and CBO's working on a not- for-profit basis etc. are now major stake holders in Health care research and delivery. The National Health Research System would recognise their important role in health research and shall foster their participation in the system as partners. These engagements have to be concurrent and intense rather than linear and loose.

4. Strengthen International Linkages

In the current global scenario International collaborative efforts are recognised as one of the factors in successful research because of the complimentarity of technology transfer, capacity building and access to diseased populations. There are a large number of potential partners and in the choice of partners the priorities of the National Health Research Plan and national interest shall be paramount. Linkages with International Developmental partners and WHO and other UN Agencies shall be further developed and strengthened to ensure that India plays a legitimate role as an emerging economy.

5. Ensure Ethical Research

The Bill on Research on Human Subjects and establishment of the National Biomedical Research Authority therein along with the guidelines developed by other agencies shall regulate all research. The Health Research System shall review these Guidelines from time to time, and harmonise them with International Guidelines. Facilitation of training in ethical research shall be the responsibility of the DHR. A major achievement has been the establishment of a National Clinical Trial Registry and all clinical trials are mandated to be registered by the DCGI.

6. Ensure Targeted Financing

The National Health Research System shall be responsible for ensuring equity in resource mobilisation and allocation of public funds. It shall endeavor to ensure that the allocation/ expenditure on health research is at least 2% of the allocation / expenditure on health. International funds will also be mobilised in keeping with the priorities. The NHRS would track the resources available and spent on research in the country and monitor its impact on health. Though a minimum of 2% of health expenditure has been achieved, this may be too small a figure considering that the allocation for health itself is meagre in relation to the population and health concerns of the country.

7. Monitor and Evaluate impact of health research

To ensure that resources are used efficiently and in line with agreed priorities there is a need for continuous monitoring and evaluation. The health research system will develop explicit policies and procedures for reviewing proposals,

and for monitoring and evaluating the output and impact of those that are funded. Indicators will be developed to monitor the development and effectiveness of the health research system. Indicators would also be defined for assessing health status, health system effectiveness, efficiency and affordability, in order to capture the contribution of research in reducing inequities. Direct indicators of National Development, would serve as indirect indicators of the efficacy of Health System research as a vehicle of development. Set mechanisms to ensure that best practices are encouraged, and practices are evidence based.

8. Partnership with State health system.

Encourage health research within States. Help set state level health research system by strengthening partnership between central and state systems.

9. Assess Health Research System

The health research system would need to be assessed periodically to provide evidence that it is functioning optimally. A suggestive strategy for the assessment of the health research system is given below:

Strategy for Assessment of the Health Research System

In view of the plurality of the health research system, the strategy for assessment must have a much broader perspective in dealing with multiple stakeholders of research funding agencies, leaders, managers and research investigators in the system. The proposed research architecture is expected to contribute to the strategic vision and goals of the health research system that can be assessed against a set of criteria. The following criteria are proposed :

Robustness: The architecture of the health research system should be such that it should advance health research for development. All the organizations within the health research system should pay attention to the goal of equity. The National Health Research Management Forum should ensure the comprehensiveness of the national research architecture.

Competence and Effectiveness: The structure should allow the formulation of a coherent strategy for achieving reasonable scientific goals. The system should have competent technical advisory committees and ethics committees to ensure the achievement of the goals and means. For quality research, there should be mechanisms to review protocols objectively through peer review processes. There should be research committee to monitor the progress of the research. Further, every research organization must have its own research, administrative and audit system adapted from well-tested practices and experiences of others. Apart from using research for policy and programs, emphasis

should be given to publication of research findings in internationally peer-reviewed scientific journals.

Credibility and Accountability: The research system should be responsive and sensitive to the concerns of various stakeholders. For this, appropriate mechanisms would be developed to get feedback and disseminate evidence among stakeholders of the health research system. The research system should hold forth the promise of achieving the goals of equity and development through not only good quality research, but also cost-effective research. There should be good financial auditing of research to ensure fiscal responsibility and accountability. The health research system should provide a high standard of stewardship.

Ability to Champion the cause of Health Research for Development: The research structure should be able to articulate effectively the significance of health research for development at various levels. Such an effort should start at the National Health Research Forum and move down to community level.

Ability to Generate Research Funding: There should be a conscious effort to set aside a significant proportion of funds of health programs for health research. Research organizations should be able to attract funding through their credibility from international funding agencies. Government should provide tax and other incentives for the private sector setting aside research funds.

Research Governance and Management: A responsive and responsible governance and management structure needs to be developed in every research institution. This may be in the form of governing bodies or oversight bodies or auditing mechanisms. While facilitating the goal of development and equity, it should also show the responsibility and accountability to the stakeholders in terms of quality of research and financial accountability. Such a body will also strictly monitor the ethical aspect of health research.

Cost-effectiveness: Stewardship, quality assurance, administrative and financial audit should be in place to ensure increased yields in research productivity and financing as well as in meeting the broader goals of health research for development and equity. Timeliness of conducting research should be ensured.

The NHRS shall be managed by a **National Health Research Management Forum (NHRMF)**.

The National Health Research Management Forum (NHRMF)

The National Health Research Policy envisages a System wherein all present and prospective players have their own space. However, an overarching National Health Research Management Forum is proposed, having representation of all key stakeholders, the DHR as its Secretariat, and the following functions / terms of reference:

- i) To advise on and evolve national health research policies and priorities and to evolve mechanisms and action plans for their implementation;
- ii) To develop a 5 year projection of the plans for health research and to prepare an annual National health research plan;
- iii) To do a mid-Plan appraisal for course correction, as needed
- iv) To promote the development of health research activities in the country;
- v) To review biomedical & health research management, and suggest strategies to overcome problems in implementation of policies;
- vi) To suggest mechanisms to nurture a scientific environment to attract talent and to develop human resources for biomedical and health research; and
- vii) To facilitate utilisation and dissemination of research results and advocacy for Health research

The NHRMF will be Chaired by the Minister of Health & Family Welfare and Co-chaired by Minister of Science & Technology. The Minister(s) of State for Health would be the Vice-chairperson(s). The Secretariat shall be in the DHR and its Secretary shall be the Member-Secretary. All Secretaries of various Departments in S&T would be the members, DGHS and 8-10 eminent scientists/public health experts (numbers flexible) as well selected representatives from State Governments would be the other members. These experts would also be the Chairmen of the various working groups which would be constituted to address the following areas:

1. Development and evaluation of interventions for promotion, restoration, maintenance and protection of health.
2. Human resource management and infrastructure development
3. Knowledge management
4. Encouragement to translational research and originality in basic science research, and innovations
5. Optimizing intra- and inter-sectoral networks, coordination and collaboration especially with private sector and industry.
6. Track current resource flow and future requirements to address priority areas of health research.
7. Establishment of priorities for health research.
8. Implementation of health research policy, planning, monitoring and evaluation.

Responsibilities of NHRMF

Stewardship

This would encompass a range of activities for the national health system intended to ensure quality leadership, productivity, strategic direction and coherent action. Sub-functions would include Strategic Vision, Policy Formulation, Priority Setting, Performance and Impact Assessment" Promotion and Advocacy, and the setting of norms, standards and frameworks for the sound practice of research. Provide best practices for research management.

Financing

The essential functions of the System as regards finances would be to address issues related to resource generation, targeted allocation and judicious utilisation. On the basis of recommendations of the National Health Research Management Forum, funds would be allocated in ways that are consistent with national priorities. External Partners would be apprised of these priorities, while a national capability to monitor where and how research funds are being spent, and the quantities involved, would be created and put in place. Ensure that funds are spent where the burden of disease is. Efforts would be made to invest at least 2% of national health expenditure in research and research capacity strengthening.

Knowledge Generation

The research system would generate knowledge relevant to the Indian health situation, appraise the measures available for dealing with health problems, and suggest the actions likely to produce the greatest improvement in health.

Utilisation and Management of Knowledge

The Research System fully endorses the principle that the research process does not end with Knowledge Generation, but includes the translation of results into policy or action, or absorption into the existing knowledge / technology base. For this to happen, links will be strengthened between researchers, policy makers, health and development workers, non-governmental organisations, communities, and media. Vertical and horizontal connectedness will be improved upon. More specifically, for better utilisation and management of knowledge, an information culture would be fostered, supported by enhanced use of information technologies currently and likely to be available. A synergy with Knowledge Management Policy would be made.

Capacity Development

A long-term approach to the development and maintenance of research capacity will be adopted. Efforts will be focussed on both the quantity and quality of skills available / needed, including research techniques, research priority setting, research management, use of research ('demand' side), policy and systems analysis, communications, development of partnerships including medical colleges and rural health research centres. A situation analysis done periodically would ensure a phased and realistic plan for constructive and sustained capacity

development. Thus, both the 'Supply' and 'Demand' sides of the research system needs will be addressed. Encourage policy research.

The 10-point Action Programme

Health is a fundamental right of all people. An evidence base developed by appropriate research should be the basis of Health Systems and Services. The global imbalance in the allocation of resources for Health research, the 10/90 Dis-equilibrium, has resulted in a low priority for research on the pressing health problems of much of the developing world. India is fortunate that significant resources are allocated for research and that funds are available in a diversity of fields and disciplines to be used for Health Research.

- 1. Harmonise optimally National policies in a variety of areas (education, social sciences, population, agriculture, nutrition, science, etc) to facilitate intersectoral collaboration and partnership, so that maximum developmental returns can occur from health research.**

Health as a developmental mechanism is truly intersectoral and harmonisation and coordination is essential for realising its full potential.

- 2. Ensure true inter-sectorality of health research and harness the resources in areas such as social sciences, economics and traditional systems of medicine.**

Health is not just the concern of modern medical science. Health research should be holistic and ensure that resources in anthropology, sociology, economics and education are optimally used to solve the real problems of the people.

- 3. Facilitate priority setting to guide the direction of health research and prepare Five-year Plan and strategy documents**

Priority determination in health research is an on-going process and has to be done at regular intervals. Groups of experts would be convened in individual areas (example communicable diseases, non-communicable diseases, maternal and child health) and also multidisciplinary expert groups including social sciences, health economic etc. these groups would identify priorities linked to setting goals to be achieved in a time bound fashion.

- 4. Encourage the development of fundamental and basic research in areas relevant to health to ensure that a national critical mass of scientists who can contribute the benefits of modern technology to health research is created.**

A critical mass of health researchers can only be built up by developing a research culture in the educational institutions. Health research would be incentivised. Originality and innovation would be encouraged. This would

require strong links between medical colleges, industry and research institutions and close supervision by the National Health Research System. Mechanisms favouring seamless movement of personnel between teaching, research and industry. Schemes to train, maintain and retain skilled human resource would be developed and implemented.

5. Foster translational research to ensure that the products of basic research can be appropriately utilized in health systems and services.

Findings of basic and laboratory research have to be translated so that they can be applied to promotion of public health including improving access to tools. This would require a diversity of expertise in addition to basic science such as epidemiology and clinical research.

6. Establish linkages between health research and national health programmes to identify key operational issues and facilitate the operationalisation of evidence based programmes and to obtain feedback for the optimisation of health research

The evidence available for health strategies would be operationalised. Links between the research community and the service components would be strengthened. The operational research necessary for this, based on a full understanding of National Programs, is one of the responsibilities of the researchers.

7. Build and integrate capacity for research in National Health Programs, research institutions and in the private sector (profit and non-profit organisations) both in rural and urban research settings utilising as far as possible areas of excellence already available in the country.

The technological, information and research excellence already in the country would be recognised and form the basis of a major capacity building process to enhance the quantum of relevant research carried out in the country. Where essential, International resources would be judiciously used for capacity building.

8. Ensure that the global knowledge base is available for national programmes, and that research is channelled in relevant directions without unnecessary duplication by the optimal use of information, communication and networking technology.

There is a large volume of research results available globally and it is essential to ensure that national research does not unnecessarily duplicate available evidence which only requires operational research to be implemented in national programs. The optimal use of modern I, C & N technology is essential for this. A beginning has been made by the

National subscription to the Cochrane Review and the access to consortium of e-libraries.

9. Manage global resources and transnational collaborations optimally to ensure that collaborative health research primarily facilitates the development of national health systems and services.

The world is developing into a global village, but there is a danger that in all research sponsored transnationally, priorities may not be focussed on National needs. The policy would require that the paramount nature of the priorities of the national health system and services as well as the ethics of international collaborative research is ensured.

10. Generate the evidence-base for health systems and services, to be significant promoters of equity and contribute to national development so that health research becomes a poverty reduction tool.

Health is not merely the absence of disease and a healthy population is the basis of national equity and development. The aim of research is to produce the evidence base necessary for optimum health systems and services. In addition to active in-country research, this would involve critical review of the global evidence base, its adaptation for National conditions and communication to policy makers.